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CERVICAL CANCER AND HUMAN PAPILLOMAVIRUS

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HEARING

before the

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES

of the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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CERVICAL CANCER AND HUMAN PAPILLOMAVIRUS

THURSDAY, MARCH 11, 2004

House of Representatives,
Subcommittee on Criminal Justice, Drug Policy and Human Resources,
Committee on Government Reform,
Washington, DC.

The subcommittee met, pursuant to notice, at 11:05 a.m., in room 2247, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings, Waxman, Davis, Norton, Sanchez, and Ruppersberger.

Staff present: J. Marc Wheat, staff director and chief counsel; Roland Foster, professional staff member; Nicole Garrett, clerk; Phil Barnett, minority staff director; Sarah Despres and Tony Haywood, minority counsels; Jean Gosa, minority assistant clerk; and Naomi Seiler, minority staff assistant.

Mr. Souder. Good morning. Thank you for being here.

Today's hearing will examine the latest medical science regarding cervical cancer and ongoing Federal efforts to treat the disease and prevent infection from the virus that causes it.

Each year in the United States, over 12,000 women develop cervical cancer and more than 4,000 women die of the disease. By way of comparison, about the same number of women die from HIV/AIDS ever year.

In 2001, cervical cancer was estimated to be the 12th most commonly new diagnosed cancer among women in the United States. According to the American Cancer Society, non-invasive cervical cancer may be four times as widespread as the invasive type.

Experts agree that the infection by certain strains of human papillomavirus [HPV], is the primary cause of nearly all cervical cancers. HPV infection is also associated with other cancers and more than 1 million pre-cancerous lesions.

About 20 million Americans are currently infected with HPV. An estimated 5.5 million Americans become infected with HPV every year, and 4.6 million of these are acquired by young Americans between the ages of 15 and 24.

In 1988, Dr. Stephen Curry from the New England Medical Center said HPV ``is rampant. If it weren't for AIDS, stories about it would be on the front page of every newspaper.''

Fifteen years later, most Americans still have never heard of HPV, and most are unaware of the dangers the virus can pose or how to protect themselves against infection, and it is still rampant.

On Monday of this week, researchers reported that an alarming one-third of women in a recent study were found to be infected with a strain of HPV linked to cervical cancer.

In January of this year, the Centers for Disease Control and Prevention issued its first-ever comprehensive HPV prevention report. The CDC report states: ``Because genital HPV infection is most common in men and women who have had multiple sex partners, abstaining from sexual activity (i.e., refraining from any genital contact with another individual) is the surest way to prevent.''

It continued: ``For those who choose to be sexually active, a monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections. For those who choose to be sexually active but who are not in a monogamous relationship, reducing the number of sexual partners and choosing a partner less likely to be infected may reduce the risk of genital HPV infection.''

The CDC reports that ``The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection.''

The CDC's findings echo a 2001 report entitled ``Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention'' prepared by the National Institute of Allergy and Infectious Diseases in consultation with the Food and Drug Administration, the U.S. Agency for International Development, and CDC, which evaluated all published data on latex condoms and STD prevention and concluded that ``there was no evidence that condom use reduced the risk of HPV infection.''

These scientific findings are important because Public Law 106-554, signed by President Clinton on December 21, 2000, requires the CDC to educate the public and health care professionals about HPV prevention and directs the FDA to ``reexamine existing condom labels . . . to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV.''

Because of the lack of awareness of HPV, there has been much confusion about the virus. I would like to emphasize two important points.

First, not everyone infected with HPV will develop cancer, but those with persistent, high risk strains of HPV are at increased risk. And second, while treatment can prevent the progression of cervical cancer, treatment should not be confused with HPV prevention. Treatment is often invasive, unpleasant, and costly, and does not include the necessity for additional treatments or adverse side effects.

Today I look forward to learning what efforts Federal agencies are taking to protect the public against HPV and cervical cancer, and, in particular, what actions the CDC is undertaking to promote the agency's HPV recommendations.

I also look forward to an update on the status of Federal programs to diagnose and treat cervical cancer and to develop an effective HPV vaccine. Congress has passed a number of laws over the past decade to increase access to testing and treatment. Because deaths from cervical cancer are largely preventable, it is vitally important that women have access to and are routinely screened for HPV and cervical cancer, and, if necessary, treated.

Finally, I look forward to hearing from the experts on our second panel, who are on the front lines every day treating patients with HPV and learning what advice they may have for Federal policymakers for improving efforts to educate, prevent, and treat HPV and cervical cancer.

Thank you all for being here today, and we look forward to your testimony and insights on this very important issue.

[The prepared statement of Hon. Mark E. Souder follows:]

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Mr. Souder. I would now like to yield to our distinguished ranking member, Mr. Cummings.

Mr. Cummings. I want to thank you, Mr. Chairman, for holding this hearing today on this women's health issue, cervical cancer.

Fifty years ago, cervical cancer was a leading cause of cancer death among women in the United States and around the world. Thanks to advances in cancer screening and treatment, the threat of mortality from cervical cancer has been dramatically reduced in the United States. Still, thousands of women are newly diagnosed each year and the American Cancer Society estimates that nearly 4,000 women will die from it in 2004.

The risk of illness and death from cervical cancer is spread unevenly among women in the United States. Despite improved screening rates enabled by congressionally authorized CDC screening programs, unequal access to screening remains a problem that contributes to significant disparities in cervical cancer rates along the lines of race, educational level, income, and age.

Women who belong to racial and ethnic minority groups are disproportionately represented among the new cases of cervical cancers. Asian, African-American, and Hispanic women have significantly higher mortality rates from cervical cancer than White women; women with less than a high school education are less likely to have testing than more highly educated women; and despite the peak in incidence of cervical cancer among women 40 to 55 years old, women in this age group are less likely to have been screened than a younger woman.

As chairman of the Congressional Black Caucus, I am particularly disturbed that African-American women are 60 percent more likely to have cervical cancer and 33 percent more likely to die from it as compared to White women.

The great tragedy in the American Cancer Society's estimates of thousands of lives that will be lost is that these deaths are indeed avoidable. The Department of Health and Human Services notes in its Healthy People 2010 initiative that the likelihood of cervical cancer survival is nearly 100 percent if early detection is followed by appropriate treatment and followup. But cost remains a barrier to access to Pap tests and DNA tests for HPV that, when used together, can accurately determine whether a woman is or is not at risk for cervical cancer or precursor conditions.

Any discussion of cervical cancer must involve HPV because genital HPV infection is a necessary precursor for cervical

cancer. But, too often, discussions about HPV devolve into discussions of the merits of abstinence-only education. Some of my colleagues believe abstinence-only education is the answer to transmission of HPV and STDs in general, despite the lack of evidence that such programs are effective and the accumulating body of evidence to the contrary.

I expect that we will hear a lot of discussion today about condoms and the CDC's recent report finding that condom use is not supportable as a primary prevention strategy for genital HPV transmission. Far more relevant to the lives of women at risk of cervical cancer is CDC's finding in the same report that condom use is effective in reducing the risk of cervical cancer. This finding speaks to the bottom line question, which is: How do we effectively preserve and protect the lives of women?

HPV, when it doesn't lead to cervical cancer, is not life-threatening. An estimated 75 to 80 percent of Americans will have an HPV infection at some time during their lifetime. In the vast majority of cases the infection will resolve spontaneously. A tiny percentage will be at risk of developing cervical cancer or pre-cancerous conditions, however. Identifying these women and, where necessary, providing treatment is critical.

The most important message that can come out of today's hearing is that cervical cancer can be prevented, detected, treated, and cured, and that health screening and condom use are essential components of a sound, realistic public healths strategy for combating cervical cancer and the spread of sexually transmitted disease.

Until we have done all we can to expand access to screening and treatment, and until there is evidence that abstinence-only education programs are effective, conversations about condom efficacy for HPV will continue to be an unconstructive sidebar to the important matter of erasing the threat of cervical cancer.

Indeed, it is worth keeping in mind that we made enormous strides in reducing cervical cancer deaths even as the so-called sexual revolution was occurring. Ensuring that cervical cancer death rates continue to go down for women in all parts of American society is what matters most. The only certain way to do that is by devoting more resources to what we know works: providing screening and treatment for women at risk. This should remain the foundation of a public health strategy for cervical cancer that puts health and wellness before religious and social ideology, and science before politics.

Thank you again, Mr. Chairman, for holding a very important hearing. I sincerely hope that we will have an opportunity to listen to our witnesses very carefully and make progress with regard to this illness that affects so many women in our country.

I yield back.

[The prepared statement of Hon. Elijah E. Cummings follows:]

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Mr. Souder. Thank you.

I would now like to recognize Mr. Waxman. I was going to recognize you next, because you are the senior ranking member on the full committee. Then I would go over to this side.

Mr. Waxman. Well, you are all very kind to let me proceed with my opening statement.

I am pleased to be here with the members of this subcommittee.

When it comes to human papillomavirus [HPV], public health policy must start with a single question: How can we reduce the rate of cervical cancer in the United States?

And this is a critical question because HPV causes cervical cancer and cervical cancer kills nearly 4,000 women in this country every year.

So I think to address this question we have to look at what works.

First, evidence demonstrates that the Pap test works. It is a simple test that can find precancerous lesions, pointing the way for treatment that can prevent invasive cervical cancer from ever developing.

It is a tragedy that about half the women with newly diagnosed cervical cancers have never had a Pap test. Expanding access to this service is an important public health priority.

Second, evidence demonstrates that condoms work to prevent cervical cancer. The CDC has found that condom use is associated with lower rates of cervical cancer. It is critically important that the public be aware of this potentially life-saving information.

Third, evidence demonstrates that comprehensive education can reduce sexual risk-taking that may lead to sexually transmitted diseases like HPV. These education programs typically stress the importance of abstinence, but also provide information on other options as well.

It is important to look at the question of how we can reduce the rate of cervical cancer in this country. I am concerned, however, that today's hearing will not focus, as it should, on this question. Instead, I am concerned that this hearing will, instead pursue a different question entirely: how the science of HPV can be used to advance the ideological agenda of abstinence only education.

This is neither a useful question, nor a new one. For years, those who have argued that teenagers should not be taught about the full range of options available to prevent unwanted pregnancy and sexually transmitted diseases, including abstinence and the proper use of condoms, have used the example of HPV to try to undermine public confidence in any other approach other than abstinence.

The main argument is to point out again and again and again that condoms are not proven to reduce the number of HPV infections. Therefore, the argument goes, condoms should carry warning labels and, ideally, should not be used at all.

Well, it is true that condoms have not been proven to reduce the risk of HPV infection. However, what is more

significant is that condoms are associated with less cervical cancer, which is, after all, the key reason we care about HPV infection.

Moreover, and this is very important, condoms, when used consistently and correctly, are very effective in preventing HIV infection, and can also reduce the risk of transmission of other sexually transmitted diseases, such as gonorrhea and chlamydia, as well as prevent unwanted pregnancies. Anything that undermines the effectiveness of condoms for these uses will have serious public health consequences. Are condoms perfect? Of course not. But reality requires us not to measure public health strategies against perfection, but rather to ask a key question: compared to what?

There are those on this committee and in this Congress who insist that abstinence-only education is the solution to teen pregnancy and sexually transmitted diseases because ``abstinence works each time.''

Well, the evidence, however, indicates that abstinence-only education works rarely, if at all. Independent reviews have failed to find any significant impact of abstinence-only education on real outcomes. And recently, for example, an independent study commissioned by the Minnesota Health Department found that sexual activity doubled among junior high school students who participated in an abstinence-only program. And earlier this week, a study of 12,000 teens presented to the National STD Prevention Conference found that those who pledge to remain virgins until marriage have the same rate of sexually transmitted diseases as those who do not take this pledge.

These studies are inconvenient for those who want to argue exclusively for abstinence-only approaches to public health problems, and I am concerned that we will not hear much about them at the hearing today.

So I urge my colleagues on this committee and in this Congress not to let wishful thinking take the place of facts. We must listen to experts, not try to pressure them to saying what we expect to hear. We must hear the evidence, not be bound by preconceived agendas.

And to do all this well, we must start with the right question: How can we reduce the rate of cervical cancer in the United States?

I thank you, Mr. Chairman, for this hearing, and I thank the witnesses particularly for coming and participating, and I look forward to their testimony.

[The prepared statement of Hon. Henry A. Waxman follows:]

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Mr. Souder. Thank you.

Ms. Davis, do you have an opening statement?

Ms. Davis. Yes, Mr. Chairman. Thank you so much for holding

this hearing on what I think is a very important issue. And you have already stated, as others have, the statistics of the number of new cervical cancer cases, and how many women in America die from cervical cancer. And I will just tell you that the percentage of women dying in Africa with HPV is even higher than the percentage here in the United States, where we sent condoms over to protect them from AIDS, but don't bother to tell them they could die from HPV; and I am really concerned about this alarming news.

And my colleagues have said that CDC has not proven that condoms prevent HPV, but they have proven that they might help. Well, this is not about a social ideology or a religious ideology, it is about informing women, letting them know. And to let our young girls and the women think that they are protected from these diseases by saying condoms are fine, go ahead, use them, when truly the only way they can be protected is abstinence, and that is not an ideology, it is a fact. And to hear the argument that if we let the American public know that condoms don't protect you from HPV, then people will stop using condoms, to me that explanation is totally unacceptable. We are still putting women at risk because we are not letting them know that HPV is a factor, it is a problem.

And I am looking forward to hearing the testimony of the witnesses and trying to get some of the facts, and I really, truly appreciate your having this hearing. Thank you, Mr. Chairman.

Mr. Souder. Thank you.

Ms. Norton, thank you for being here. Would you like to make an opening statement?

Ms. Norton. Thank you, Mr. Chairman, for shedding light on an important precursor to cervical cancer. I do want to say to my good chairman of the Civil Service Subcommittee, I don't think anybody here was making or would make the argument that women should not be informed of their risks that HPV bring, as well as other risks. My goodness, HPV is very, very common. Eighty percent of sexually active people show HPV. Obviously, not all HPV leads to cancer, or we would really have a cancer epidemic on our hands, but the fact that it is a precursor or means that you could get cancer is very important information.

The CDC report that has been referred to here seems to me has made clear that condoms should not be the major strategy for preventing HPV infection. That is important information to shout from the hilltops. But the CDC report was also clear that condoms reduce cervical cancer. So what we have here is what we have often in medical science, we have a preventative that doesn't prevent everything, and we better tell people about it.

Let me go on record right now as being for a better condom. Perhaps the first thing we ought to be doing is encouraging research so you get a condom that people will use and that, in fact, prevents HPV. And I say so because we all know that condoms are here to stay; they are one of the oldest, one of the cheapest, and one of the most effective methods of birth control and of disease prevention. That is a fact. They ought to be improved, because something so cheap and something so generally effective is not going to be wiped out even by telling people about the risk of HPV, and certainly not by a very important hearing.

I was impressed with the study that Mr. Waxman referred to and my staff had brought to my attention, that the teens who pledged to be abstinent showed the same rate of sexually transmitted diseases as those who did not. These are teens, in good faith, trying to do what is right. Interestingly, one of the problems, according to the study, was the so-called virginity pledgers were less likely to use condoms. Here we come back to abstinence only and to the failure to understand what we must do to in fact be where we want to be. All children, all children should abstain from sex. And disease is only one of a dozen reasons why no child should be engaged in sex. This society has failed utterly to make that point, and I don't think that anyone believes we will ever be truly successful there.

The other point, of course, is that adults should be monogamous. I regret to say we have failed to make that point as well.

With these two giant failures on our hands, we need to talk about abstinence, and we need to talk about it clearly so that children understand why. That, yes, it is for religious and moral reasons; yes, it is for preserving yourself for a mate; and, yes, it is for preventing disease, which may have a greater effect than some other reasons. But all together the information needs to be transmitted.

But if we are going to have a hearing today on cervical cancer, we certainly must say that whether you abstain or not, every woman should have a Pap smear. If you want to look at why we have reduced the incidents of cervical cancer over the last several years, you will turn to the Pap smear. So we have to have a range of interests if we are truly interested in cervical cancer.

And I thank you, Mr. Chairman.

Mr. Souder. Thank you.

I would now like to ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and that any answers to written questions provided by the witnesses also be included in the witness. Without objection, it is so ordered.

I also ask unanimous consent that all exhibits, documents, and other materials referred to by Members and the witnesses may be included in the hearing record, and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered.

Our first panel is composed of our colleague, Dr. Dave Weldon, a representative from Florida. Welcome home, former member of this subcommittee.

It is the tradition of this committee to administer an oath, but we do not do that for Members of Congress, because we already took the oath.

So you will now be recognized for 5 minutes. Thank you for taking the time to join us today.

STATEMENT OF HON. DAVE WELDON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. Weldon. Thank you very much, Mr. Chairman. It is certainly a pleasure to be in what was previously, I believe,

my hearing room when I was on the committee. And thank you very much for calling this hearing; it is a very, very important subject. And I certainly want to thank the ranking member as well, Mr. Cummings.

Sexually transmitted diseases are one of the most important health issues facing our Nation today. According to the CDC, 3 million new cases of chlamydia, 1 million new cases of herpes, 5 million cases of trichomoniasis, and 5.5 million new cases of HPV occur every year. Unfortunately, women and adolescents seem to bear disproportionately the burden in this epidemic.

Just recently, the Alan Guttmacher Institute's perspective on sexual and reproductive health published data demonstrating that almost half of all STD infections were among 15 to 24-year-olds; and HPV, trichomoniasis, and chlamydia accounted for 88 percent of all these new cases.

What is worse is that our agencies entrusted to protect public health have been slow to act effectively to prevent further spread of these costly and harmful infections. After over a decade of increases in HPV incidence, the Centers for Disease Control and Prevention only just recently determined an effective prevention policy for HPV.

The CDC's recent report states ``Because genital HPV infection is most common in men and women who have had multiple sexual partners, abstaining from sexual activity (i.e., refraining from any genital contact with another individual) is the surest way to prevent infection.'' While the CDC is to be commended for promoting abstinence as a sure means to avoid HPV infection, it has taken a long time for this common sense and science-based conclusion to be reached.

Other agencies have been quick to spend some $6 billion on research to advance methods of identifying and treating cervical cancer, but little on true primary prevention and risk avoidance. I believe this inattention to abstinence as a positive public health approach is only a symptom of a larger, more troubling phenomenon, a phenomenon that places science behind politics and social agendas. That phenomenon I am describing promotes the notion that technology can effectively mitigate our problems and that individual behavior is fixed-particularly with respect to sexual activity.

Doctors like myself are great friends of technology because it allows us to help millions who are sick and in need of treatment. Technology is good medicine because it aids in diagnosis and treatment, and can help reduce risks and costs. Nonetheless, technology is still no match to that simple ounce of prevention. Eating properly can stave off obesity and all its consequences like diabetes and heart disease; not smoking can prevent emphysema and lung cancer; and avoiding excessive alcohol can prevent liver disease. An equally important message today is avoiding sexual promiscuity can prevent not only unplanned pregnancies, but a host of incurable diseases, some of which lead to cancer and death.

We have known for years that STDs, including HIV/AIDS and HPV, are closely associated with promiscuous sexual behavior, but most of our public health approaches have sought to employ intervention modalities that reduce the rate of infection instead of true preventive strategies. Instead of seeing reductions in HIV and AIDS, chlamydia and HPV, we have seen

significant increases year after year. In fact, after hundreds of millions of dollars to eliminate syphilis, an easily preventable and treatable infection, we are now seeing syphilis incidences on the rise, particularly in many communities where specific prevention efforts were implemented. This is because we have not been engaging in true prevention; we have, in reality, been engaging in risk reduction programs. Unfortunately for millions of young people, this has resulted in neither prevention nor risk reduction, as the rate of these STDs has continued to increase.

Certainly, as a physician who has practiced full-time for 15 years before coming to Congress, and who still sees patients, I have seen on a personal level the consequences of what we are talking about today. The heartache of infertility caused by chlamydia scarring of the fallopian tubes, chronic recurring cycles of pain from herpes, and even disability and death from HIV and from metastatic cervical cancer due to HPV.

As a policymaker and as a physician, my objective is to see fewer STD infections. Currently, the predominant method to achieve that objective is clinical. The clinical approach seeks to screen and counsel as many people as possible, and to provide them with a condom in the hopes of reducing STD infections. Certainly, many of these pursuits are worth continuing and expanding aggressively.

However, as a physician, I can only see one patient at a time. A much better public health approach, particularly for behavioral risks, is to reduce the need for patients to enter my office in the first place. That is why education is so important.

My former colleague, Tom Coburn, introduced legislation that became law mandating that the CDC and the FDA educate the public about the risk of contracting chlamydia and other STDs through sexual contact. I have seen little evidence to indicate the CDC and the FDA are in compliance with this important law. Even in the area of public education, Federal programs are, for the most part, doing very little to prevent people from coming into my office.

Mr. Chairman, I believe that we need to continue to aggressively promote accurate information to all young people and adults on the true efficacy of the condom in preventing the transmission of sexually transmitted diseases and, as well, the best methods for preventing these diseases in the first place.

I thank you. I will submit my entire written statement for the record, and I would be very happy to field any questions.

[The prepared statement of Hon. Dave Weldon follows:]

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Mr. Souder. Thank you. I appreciate your comments very much. I think it is very important that we aren't defeatists. The primary role of this subcommittee is really to work with narcotics issues, and clearly in narcotics we work at prevention in the schools, we work at interdiction, we work at eradication. We have all sorts of things, in addition to

treatment questions. And if we just said, oh, well, we can't stop drug abuse, we better just treat the victims, we would have a tremendous problem. And we are seeing the same challenge here with HPV.

We have heard twice referred to in opening statements this study that recently came out. Yesterday the New York Times reported that most teenagers who pledge to remain abstinent until marriage did not keep this pledge. When compared to those teens who chose condoms, the teens who took the pledge were more likely to delay the age of sexual debut; they were more likely to be married at a younger age; they were more likely to be virgins when they married. They were also less likely to be infected with three STDs that the researchers used as markers. I would note that the researchers did not screen the study subjects for HPV. Despite the lower STD rates of those who took the virginity pledges, as compared to those who chose safe sex, opponents of abstinence education claim this study proves that abstinence education is a failure.

Could you comment on these findings and this conclusion that we have already heard here this morning?

Mr. Weldon. Well, let me start out by saying I have not seen the study in question. From what I gather, it appears to be a followup from an earlier study published by the same author, which was looking at 12,000 teenagers and showed a significant delay on the onset of sexual activity of 18 months. As I understand it, though, based on the numbers he did report, there was a reduction in the incidence of sexually transmitted diseases in the group that took the pledge. In Whites it was 2.8 percent versus 3.5 percent; Hispanics, 6.7 percent versus 8.6 percent; and in the Black community it was 18.1 percent versus 20.3 percent.

Clearly, the trend is a lower incidence, and what I think we need here is more research on this subject. But the fact that sexual activity was delayed significantly I think should not be discounted. Many of the people who are criticizing abstinence, I don't think they would recommend that I, as a physician, stop telling my patients to stop smoking because it is bad for you simply because the majority of them continue to smoke. As a matter of fact, in clinical practice it was determined that when doctors do that, a certain percentage do actually quit; and though it is very small and many doctors get discouraged, so they stop telling their patients to stop smoking, when you multiply that over hundreds of thousands of dollars over the millions of people in this country, the end result, and this is what the public health officials concluded, you can prevent hundreds of thousands of people from going on to develop lung cancer or emphysema, even though the response rate was fairly low.

Now, what I think this study is actually telling us is that you need more followup with these young people. But certainly to give up on the notion that abstinence works in preventing the onset of teen sexual activity, abstinence education, flies contrary to what the science is actually telling us. Certainly there is some very excellent data on this issue out of Africa in Uganda, that you can significantly delay the onset of sexual activity through abstinence education programs.

Mr. Souder. So in effect, if I understand what you are

saying, if this would be like a high school class took a no smoking pledge without background or other types of things, no followup with it, you would have some who might actually follow through, which is a gain.

Mr. Weldon. Right.

Mr. Souder. But you would have some who wouldn't, some who might do it less frequently, some who might not change their behavior at all. But you certainly gained in two different groups from the pledge. What you are saying is the study didn't prove any failure of abstinence education, or even of the pledge. In fact, the pledge, from their own data, did work, but that it didn't work 100 percent. And what that should suggest is that a broader abstinence education program might even get more results than just a pledge.

Mr. Weldon. I am not sure I would go as far as what you just said. I think the way I would interpret this agrees initially with what you said, that some kids will delay the onset of sexual activity. The way I interpret this is that more research is needed, and if you are going to have an effective intervention, you may need to have some kind of significant followup from the original pledge.

Mr. Souder. We certainly find that true in alcohol, tobacco, and in other narcotics, that you have to have more than just an initial pledge. That would be no surprise.

Mr. Weldon. Absolutely. Absolutely.

Mr. Souder. Mr. Cummings.

Mr. Cummings. Just to piggy-back on what was just said, when you say followup, what do you mean?

Mr. Weldon. Well, I am not intimately expert on the True Love Waits, the pledge program, but the researcher that has been tracking these kids, he was originally at Columbia and I think he is now at Yale, Dr. Berman. He originally published some data 3 years ago that showed this was working very, very effectively in getting kids to delay the onset of sexual activity. And what he did was a very nice followup study which showed, yes, they did delay, but if you actually do a surveillance study, at least in the three markers that he used, you see only a very small reduction in the incidence of these diseases in the pledge takers.

And so my question is does that mean we throw the whole concept out the window? And I say no. We need to go back and look at is there a way to make the program better, is there a way to make the program work better?

But the other point I was trying to make is if you see a 1 percent reduction in the incidence of these diseases, if you translate that over the entire population of the United States, from this study, then you may be getting into hundreds of thousands of kids that are avoiding these diseases. So does that mean we abandon it? And I would say no. I would say more research is badly needed in this, but I think it is certainly an accurate statement to be telling these kids that the best way to prevent these diseases is through abstaining from sexual activity and, in particular, abstaining from having multiple sexual partners. The data is actually the more partners you have, the more likely you are to acquire these diseases. And when you look at the fact that some of the diseases they can contract can be fatal, I think it is a message that is

definitely worth giving our young people, because we are telling them the truth.

Mr. Cummings. Well, I want to go back to something Ms. Norton said, because I don't want us to be confused here. I don't see that there is anything wrong with saying you should abstain. I think the question becomes for that person who does not decide to abstain. I have gone into high schools, and I remember one time I went to a middle school, and I thought I was pretty hip.

Mr. Weldon. I thought you were too.

Mr. Cummings. And I was telling these young people that it is very difficult to progress when you have a baby on your back. And after the thing was over, and this was in middle school, some kids came to me and said, Mr. Cummings, we like you and everything, but you don't know, but a lot of these folks are already involved in sexual activity, and you really didn't sound too hip up there. And I continue to say those things, but while we may want a certain thing, I think we also have to deal with a dose of reality, too, in some other instances. And I think that is one of the points Ms. Norton was making. And I use the analogy that when my 21-year-old daughter was 3 years old, she used to like to play hide and go seek. And she would come up to me and she would put her hand up to her face, and she would say, daddy, you cannot find me; and she was right in front of me. And I think we have to deal with the reality that as much as we might like to see our young people abstaining, that simply is not always the case, and so then I think you then have to say, OK, if they are not abstaining, then what advice do you give.

Mr. Weldon. Well, that is a great question. I think, as a policymaker, that should be the purview of local school districts, parents, teachers, churches to get engaged on that issue. The primary concern that I have had for years is an over-aggressive emphasis on a condom as a solution to the problem ignores the scientific fact that compliance with condom use amongst 15 to 24-year-olds is extremely poor. You can't take the condom data based on HIV discordant couples in their 30's and 40's, where you are talking about one spouse has it, one doesn't, where you get compliance rate with condom use at 99 percent, you cannot take that data and extrapolate it to these kids, the ones we are really talking about now, because that is when they contact HPV, it smolders for years, and then it becomes cervical cancer later in life.

And so I think you need to give the kids the full message, and the full message is that the condom, No. 1, is not a sure way to prevent some of these diseases; and the best way to prevent all these diseases is through abstinence, understanding that a significant number of them will not be able to comply. At least we should give them the message.

Mr. Cummings. Thank you.

Mr. Souder. Mrs. Davis.

Mrs. Davis. I think Dr. Weldon just said what I would say. It is very disturbing to me that you have 4.6 million of the 9 million new STD cases were 15 to 24. And, to me, when we send the money down to the local schools, or what have you, to make the condoms available to these kids, and that is what they are, kids, and, yes, reality is they are sexually active, but I

think we need to, to quote Ms. Norton, we need to yell it from the top of the rooftops that these condoms we are sending down to you don't protect you. And I don't think we are doing that. I think what we are doing is saying, well, you should abstain, but just in case you can't, here is the condom. And we don't tell them what the possible effects will be using the condom, so they have a false sense of security. So I think we are sending the wrong message when we use taxpayer dollars to give condoms out to these kids and we don't tell them, by the way, you are probably going to be dead maybe at age 24 by cervical cancer, but we are giving you the condoms, so go do your thing. To me, abstinence is the only way.

Mr. Weldon. If I could just add one more thing. You know, this is a social problem that goes beyond sex education. There are some dynamics here that we have little or no control over, specifically, some of the messages that come through our culture, particularly on the television, in the movies, out of Hollywood, and the truth is the sexual revolution is a bit of a lie in that totally unfettered sexual liberty indeed can lead to significant disability and death and poverty, as Mr. Cummings was alluding to with the burden of trying to raise a child as a single mother. However, we have first amendment issues there that run contrary to us trying to constrain those kinds of bad messages getting out in our culture.

Mr. Souder. Would the gentlelady yield to me for a second?

I wanted to followup with your smoking example. I have certainly been to schools where the majority of the kids were smoking, and increasing numbers in some schools, particularly younger ages and young girls. And I certainly favor more treatment for the results of that smoking, but I don't back off my message because it is going younger and increasing. I don't understand the philosophy that says we should not deliver the primary message.

Mr. Weldon. Well, you are absolutely right. And I haven't looked at the more recent data, but as I understand it, smoking rates are going down.

Mr. Souder. Overall.

Mr. Weldon. Overall. And the incidents of smoking-related diseases in some categories, I believe, appears to be trending downward. And when you think about it, this is a phenomenon that we are finally starting to see based on 30 or 40 years of effort in the public health arena, which began with the little labels on the cigarette boxes and now employs some very, very sophisticated Madison Avenue-type messaging going out to young people, a lot of the money for that coming through this tobacco settlement.

I believe if we earnestly apply ourselves, we can turn this problem around. Certainly, to turn our back on it and ignore it would be a tragedy. And to continue to do what we have been doing in the past is equally a tragedy, because the rates are going up. And so we need to step back and say what we are doing is not working; we need to try something new. And I think the abstinence messaging, and if you look at the experience in Uganda, where I think you had a very nice national program to get out a message of abstinence and you did see a significant reduction in at least HIV that was tracked, I think there is plenty of reason to continue to pursue this agenda.

And if you read the news reports on that study that has been quoted by some of the people on the minority side, published in the New York Times, if you read deep into the study, people acknowledge that we need more research on this issue, and I think we certainly do. And the people who are giving an abstinence message need to really look at this research very, very closely and see how they can modify their message, expand their message in a way so that it can be more effective.

Mr. Souder. Any further questions?

Ms. Norton.

Ms. Norton. You know, there is a developing consensus here, I think, that the more people, including young people, know, the better off they are. I happen to be really for telling them about disease because I think you might frighten them away from sex, and particularly since I believe that young people should not have sex. Of course, when we are talking about abstinence, we better be careful here that we are talking about young people, yes, but we are also talking about adults here. And, of course, the message of abstain doesn't make a lot of sense in today's adult world.

So if you are telling them that condoms don't work, for example, should you also tell them that abstinence doesn't also work? Also sometimes doesn't work?

Mr. Weldon. Well, abstinence is 100 percent effective when it is practiced 100 percent of the time.

Ms. Norton. Yes, the day it is practiced. How about the next day when it is not?

Mr. Weldon. That is a scientific fact. Ms. Norton, I did physical exams on elderly women going into nursing homes, and maybe this is a different era, who confessed to me that they had never had sex in their entire life. People can abstain. It is something that actually goes on. It may be totally disbelieved by Hollywood.

Ms. Norton. Well, you are not advocating abstinence for adults, are you?

Mr. Weldon. Well, here is what I really wanted to say. If you look at the success in the condom in preventing the transmission of diseases like gonorrhea, syphilis, and they haven't studied HPV, but the data on gonorrhea and syphilis is pretty clear in this age group that we are talking about.

Ms. Norton. What age group are you talking about, sir?

Mr. Weldon. Fifteen to 24-year-olds. The efficacy on the condom in preventing the transmission of gonorrhea from the man to the woman is, I think, about 40 percent or 50 percent; and from the woman to the man it is slightly better, 60 percent, in that range. And I think the syphilis data is somewhat similar. And I don't want to get into the excruciating details of the path of physiology of the transmission of these diseases, but I think we owe it to young people to tell them those facts, that the data on the efficacy of the condom is not 100 percent.

Now, part of the problem, and this is something else that we need to explain to young people, with this issue of how well these things work is that it is very hard to get into 100 percent compliance mode. They will use the condom some of the time.

Ms. Norton. And they will use abstinence some of the time.

Mr. Weldon. Well, basically, anybody who is engaging in being sexually promiscuous is just not being abstinent.

Ms. Norton. How about having sex once and getting HPV? I mean, the notion of calling everybody who falls off the wagon for abstinence promiscuous is, I think, an insult to human nature. Sometimes people fail. We all fail sometimes.

Mr. Weldon. I am not doing that. What I am talking about is if you look at who gets these diseases, the correlation is the increased number of sexual partners you have. OK? As you have more sexual partners, you are much more likely to contact HPV, HIV, and a whole host of other diseases. And if you are doing it without, obviously, the use of any type of contraceptive or a condom, the incidence rates go much, much higher.

Ms. Norton. The notion of letting the information flow is something that, particularly on this part of the isle, we have been for sometimes meeting, if I may say so, concerns on the other side of the isle when business comes and says they don't want certain kinds of things on labels. So, indeed, I would like to ask you do you think it would be a good thing to put on the labels of condoms that it does not prevent HPV?

Mr. Weldon. Yes, I do. And I think it would also be appropriate to put the label that it is not 100 percent effective in preventing the transmission of gonorrhea and syphilis. That would be another reasonable thing to put on there.

Ms. Norton. You know, I knew that if we kept this up, Mr. Weldon, you and I could find our points of agreement. We just found it. Thank you very much.

Mr. Souder. Thank you.

We have been joined by Congresswoman Sanchez from California, and I will yield to her for any statement and questions.

Ms. Sanchez. Thank you very much. I just want to have a brief sort of comment, and then I will get ahead to my question.

I think sort of the analogies that are being drawn here, between smoking and sex and abstinence, I don't think the messages need to be mutually exclusive, either or. I think when you arm young people, and there are responsible young people, and educate them about abstinence, and if abstinence is practiced 100 percent, it is 100 percent effective. However, for those who don't practice abstinence, to suggest condom use may reduce significantly their chances of contracting a sexually transmitted disease, I think that is also valid. It is like saying, OK, look, I don't want to buy my kid a motorcycle and say go ride the motorcycle, but if my kid is 18, has saved up the money and bought the motorcycle, I don't want to just say wear a helmet and you will be safer. While that is true, I would want my kid, if he or she bought a motorcycle, I would want to say, OK, you need a helmet you need to take training classes, you need to understand all of the risks involved. And I think with condom use, yes, it probably is sporadic among kids that are 15 to 24 years old, because they are not given all of the information about the proper way to use it and the small risks associated with the fact that they can contract sexually transmitted diseases through improper use or for whatever failures.

But from everything that I understand, the most important risk factor for cervical cancer is not the presence of HPV infection, but it is really a failure to receive timely Pap screening and followup care. So I am interested in knowing what your thoughts are on this, because we seem to have sort of focused in on HPV and condom use, but from everything that I have read and everything that I have heard, HPV is not the biggest determinant of who will ultimately fall victim to cervical cancer.

Mr. Weldon. Well, I am not a gynecologist, I am a general internist, and so I only did probably three or four Pap smears a day in my clinical practice, where gynecologists, and I think you are going to hear from Tom Coburn, did maybe 40 or so a day in their clinical practice. And I promoted it in all of my patients in the age group at risk, to have it done every year.

The new findings have been that HPV is the cause of cervical cancer, and this has precipitated a tremendous amount of discussion within the public health community and at CDC, and as well, obviously, in the halls of Congress about primary prevention. Because when you are doing Pap smears, you are doing surveillance; you are saying we know there are millions of women out there who now have this virus, so we are going to do surveillance and we are going to catch it early using the Pap smear technology, and respond in a way that prevents them from developing metastatic cervical cancer and dying early. And we need to continue to do that, and we need to continue to do that aggressively.

Mr. Cummings' comments about access to timely health care are extremely important. We need to do more in that arena as well. But I think it is very, very interesting, can we do more in the arena of primary prevention? And what has emerged is data that suggests that you do not prevent the transmission of this disease by wearing a condom. And when I say disease, I am talking about HPV. The condom does appear to lower the incidence of cervical cancer in the group of women who are affected with HPV.

So I think what Ms. Norton was referring to, full disclosure to young people is the way we really should be going, that is the path we should be going down, and telling these kids all the facts and not just assuming a posture of, well, we can't change behavior, and give them condoms and, therefore, we will lower the incidence of these conditions. I think we need to go several steps beyond that.

The message that I have always liked has been the Ugandan message, which is try to abstain from sex and be faithful in marriage. If you cannot do those things, then, minimally, you should wear a condom, even knowing that the condom is not 100 percent effective for preventing many of these diseases.

Ms. Sanchez. Might I suggest a radical notion? That perhaps those two messages, in addition to you might want to get regular Pap smears and screening, could be a three-pronged attack toward trying to reduce the overall incidences of cervical cancer for many women in this country.

Mr. Souder. Mr. Ruppersberger.

Mr. Ruppersberger. Excuse me for not being here. A lot of committee hearings today, and after my questions I have to go to another committee hearing. I know you understand that.

Mr. Souder. Right.

Mr. Ruppersberger. We are on the same side of the isle sometimes.

Mr. Souder. Mr. Ruppersberger, Congressman Weldon has a similar problem, so if you could just ask short questions.

Mr. Ruppersberger. I will be very quick.

First, and I am not sure whether you can answer this question, is the rate of sexual activity or STDs among teenagers who have received abstinence-only education lower than among teenagers who have received comprehensive sex education? Would you be able to answer that question?

Mr. Weldon. The one thing I can tell you is that the teens that received abstinence education appear to delay the onset of sexual activity. And so the way you asked me that question, you get into the science of how you want to measure what you are talking about, and one of the measures that were used in one of the studies we were talking about previously, looking years later at the prevalence of certain sexually transmitted diseases, the difference between the abstinence group and those who didn't receive abstinence did not appear to be significant.

So I am not sure I can answer your question exactly, but it is a very well established fact that children who receive an abstinence-based education message will delay the onset of sexual activity as much as 18 to 24 months, which I think is a worthwhile accomplishment.

Mr. Ruppersberger. Well, it is my understanding the median age of marriage for women is 25 years of age, and for men I believe is 26, and that 90 percent of Americans are sexually active before age 25. Now, with that in mind, is it safe to base public health policy on strategies that require behavior that is so far outside today's normal cultural norms? And I think that is an important question, because we need to cut through all our ideological issues, wherever we are, and get to the bottom line on how we deal with the issue.

Mr. Weldon. Yes, I think there is a good rationale for providing teenagers an abstinence message, and one of the reasons is the female genital tract in teenagers is anatomically slightly different than in adults. Teenagers are much more prone to complications of sexually transmitted diseases, and so to abandon a message for teenagers simply because we don't expect adults to fully comply I think is misguided.

Mr. Ruppersberger. Well, I agree with you. I don't debate that with you, I agree with you on that.

Mr. Souder. Thank you very much.

Thank you for staying and taking the questions this morning.

Mr. Weldon. Pleasure.

Mr. Souder. If the second panel could come forth. Dr. Ed Thompson, Deputy Director for Public Health Services, Center for Disease Control and Prevention; Dr. Edward Trimble, Gynecologic Oncologist, National Cancer Institute, National Institutes of Health. And if you could remain standing as you come forward, because we will also do the oath in a minute. Dr. Daniel Schultz, Director of the Office of Device Evaluation, Center for Devices and Radiologic Health, Food and Drug Administration.

If you would each raise your right hand.

[Witnesses sworn.]

Mr. Souder. Let the record show that each of the witnesses responded in the affirmative.

Well, thank you all for coming to this wonderfully non-controversial subject.

Dr. Thompson, we appreciate it, and we will have you give your testimony first.

STATEMENTS OF ED THOMPSON, M.D., DEPUTY DIRECTOR FOR PUBLIC HEALTH SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION; EDWARD L. TRIMBLE, M.D., GYNECOLOGIC ONCOLOGIST, NATIONAL CANCER INSTITUTE NATIONAL INSTITUTES OF HEALTH; AND DANIEL G. SCHULTZ, M.D., DIRECTOR, OFFICE OF DEVICE EVALUATION, CENTER FOR DEVICES AND RADIOLOGIC HEALTH, FOOD AND DRUG ADMINISTRATION

Dr. Thompson. Thank you, Mr. Chairman. I am Dr. Ed Thompson, Deputy Director for Public Health Services.

Mr. Souder. I think you are going to have to, just like we are struggling with the mics, get as close as you can.

Dr. Thompson. I will try to swallow it. Here, how about that?

I am the Deputy Director for Public Health Services of the Centers for Disease Control in Atlanta. It my privilege to represent the CDC here today. I have two goals. One is to provide you with information, and the second is as I always do at hearings of this sort, I intend to convince you that southerners do not speak slowly.

Members of the committee and Mr. Chairman, we appreciate your holding this hearing, and we appreciate the depth of your understanding that has been reflected in the comments that you have already made about this complex issue. We have little additional knowledge to bring to you on this subject, and we acknowledge that. All of us are troubled by the number of sexually transmitted diseases and infections occurring in this country, and this problem is most disturbing when it occurs, as it too often does, among America's youth. We are absolutely convinced, and it is clear to us, that the first line of defense against STDs for this particular population is abstaining from sexual activity. We appreciate the committee's interest in the health of America's youth, and women in particular, and we welcome this opportunity to discuss CDC's activities with regard to prevention of cervical cancer and human papillomavirus infection.

As has been clearly noted, although HPV infection is known to be associated with a number of diseases, the one of, by far, the greatest public health importance is cancer of the uterine cervix, for which HPV has a causal relationship. Cervical cancer, as has been noted, and as my colleagues from the National Cancer Institute can elaborate on, can be prevented largely through screening and early detection and treatment of precancerous lesions. And when it does occur, with screening and early treatment, the success rate of treatment for cervical cancer is in excess of 90 percent.

If you will take note of the chart to my left, this shows, in the large bar, which, if it were not cut in half to fit the screen, would go above the ceiling of this room. We see the

number of human papillomavirus infections occurring in American women annually in excess of 2 million. And then we see a bar representing the number of cervical cancer diagnoses occurring each year in this country, and a bar representing, for the year for which this chart was prepared, the number of cervical cancer deaths. As noted, that number of cervical cancer cases is in excess of 10,000, and the number of deaths is approximately 4,000.

Now, the important thing that this chart shows, however, is that in spite of the preventability and the treatability of cervical cancer, we still have over 10,000 occurrences and approximately 4,000 deaths. Even more important, of these women, approximately one half have never been screened, and an additional 10 percent have not been screened within the last 5 years.

If you will look at the next chart that we are putting up over here, this shows you information from CDC's behavioral risk factor surveillance system, and it indicates clearly that as we continue to find that millions of American women still are not receiving adequate screening for cervical cancer and its precursors, this is the number of women or the percentage of American women who have been screened for cervical cancer in the last 3 years, and it has not only not reached 100 percent by a long shot, it has continued relatively the same over the last decade.

HPV infection is, as has been noted, the most common sexually transmitted infection in the United States, and, as noted, approximately 20 million Americans are infected at any given point in time, and about 5.5 million new infections do occur each year.

As illustrated on the next chart, a recent estimate suggests that as many as 80 percent of sexually active American women will have developed HPV infection at least at some point by the time they reach age 50. And you see that graphically depicted here.

A genital HPV infection is transmitted primarily through sexual intercourse, and since it is almost always asymptomatic, the usual source of transmission is someone who has no idea he or she is infected. The most important risk factor for HPV infection is clearly the number of sexual partners. For both men and women, the risk of acquiring a genital HPV infection generally increases with increasing numbers of lifetime male sex partners.

CDC has been involved in a variety of clinical laboratory and epidemiological studies of genital HPV infection for over 20 years. Public Law 106-554 included new provisions for CDC with regard to HPV, and since the enactment of that law we have undertaken additional activities. These have included sentinel surveillance to determine the prevalence in various age groups and populations of specific types of HPV; the collection of additional national prevalence and surveillance information using CDC's National Health and Nutrition Examination Survey [NHANES]; the initiation of several formative research activities to assess knowledge and attitudes of the public and of HPV-infected individuals about HPV; and the completion of formative research to develop a survey to assess knowledge, attitudes, and practices of health care providers regarding HPV

diagnosis and treatment.

The status of these activities and timeline for this completion were outlined in August 2003 in a report to Congress titled ``Human Papillomavirus: Surveillance and Prevention Research.'' A copy of that report was sent to the committee, along with the written testimony we provided to you early this week.

Now, the photograph that you see here shows one of many CDC laboratory activities conducted on HPV. CDC has conducted laboratory research on clinical outcomes of HPV disease, prevalence and risk factors for HPV, biological markers of cervical cancer and HPV, and development of sensitive HPV diagnostic tools.

CDC's National Breast and Cervical Cancer Early Detection Program provides cancer screening for under-served and uninsured women. Approximately one-half of the women receiving services through this program are from racial and ethnic minority populations. Since its inception, this program has identified over 55,000 women with cervical cancer precursors, and approximately 1,000 with cervical cancer.

In January of this year, CDC submitted a report to Congress titled ``Prevention of Genital HPV Infect,'' summarizing available science and making recommendations about strategies to prevent HPV infection and cervical cancer. A copy of that report was provided to the committee as well, along with the testimony that you have received.

I can summarize the recommendation from that report if it is the committee's pleasure. If not, I would like to thank the committee again for this opportunity to describe CDC's activities with regard to HPV and cervical cancer, and I am prepared to answer any questions the members may have at the appropriate time.

[The prepared statement of Dr. Thompson follows:]

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Mr. Souder. Thank you very much. You did prove southerners can talk really rapidly, but not like we Yankees.

Dr. Trimble.

Dr. Trimble. Chairman Souder, on behalf of Dr. Andrew von Eschenbach and the National Cancer Institute, we would like to thank you for this opportunity to testify on HPV and cervical cancer. I am Edward Trimble, an obstetrician-gynecologist and gynecologic oncologist working at the National Cancer Institute.

A hundred years ago, cervical cancer was the leading cause of cancer deaths among women in the United States. Since the identification and adoption of effective screening for cervical cancer with the Pap smear, based on our understanding of the natural history of precancerous changes in the cervix, we have been able to reduce both incident and death rates from cervical cancer dramatically in the United States and elsewhere in the developed world.

Over the past century, we have learned much about the natural history of cervical neoplasia or abnormal cell growth. We have learned that cervical cancer is preceded by precancerous changes in the cervix. We have learned that treatment of these precancerous changes can prevent the development of cancer. We have learned that a Pap smear taken from the cervix can identify these precancerous changes. More recently, we have identified the human papillomaviruses as the major cause of cervical cancer. Studies also suggest that HPVs may play a role in cancers of the anus, vulva, vagina, and penis, and some cancers of the throat. There are more than 100 types of HPVs, of which only 30 can be transmitted by sexual contact. HPV is one of the most common sexually transmitted viruses. Only rarely does an infection with high-risk HPV develop into pre-cancer or cancer. The majority of HPV infections go away on their own and do not cause any abnormal cell growth.

The NCI has made a strong commitment to understanding the causes of cervical cancer and the relationship of HPV viruses to the development of cervical cancer. In fiscal year 2003, we spent $79 million for research on cervical cancer. We have funded extensive research to understand why most adults exposed to the HPV virus do not develop cancer or any other health problems resulting from that infection. NCI scientists have developed a new vaccine approach to prevent infection with HPV and are also working to develop a therapeutic vaccine to protect women already infected with the virus from developing cancer. In addition, NCI has worked extensively to improve the

reliability of Pap tests, to evaluate new methods of screening for cervical cancer, and to combine testing for HPV with Pap tests. NCI is also committed to working to improve treatment for women diagnosed with cervical cancer. In 1999, we issued a clinical announcement to alert women and their doctors of a major treatment advance, combining chemotherapy and radiation in cervical cancer. NCI investigators are also working to preserve fertility in women with early cervical cancer, as well as to reserve bladder, bowel, and sexual function after treatment for cervical cancer. Finally, we have increased our support for research to address the gaps in the delivery of treatment research advances to all populations. We are building long-term relationships between research institutions and community-based programs to learn more about the causes of cancer disparities across the United States and develop ways to eliminate these disparities. In the future, as part of NCI's challenged goal to eliminate the suffering and death due to cancer by 2015, we plan to continue our close collaboration with our sister agencies, to make available effective vaccines for HPV, to reduce the emotional and economic costs of screening for cervical cancer, to improve the accuracy of screening, and to find more effective treatment for cervical cancer.

My written testimony contains additional details on our research program. I would be happy to answer any questions you might have.

[The prepared statement of Dr. Trimble follows:]

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Mr. Souder. Thank you very much.

Dr. Schultz.

Dr. Schultz. Good morning, Mr. Chairman and members of the subcommittee. I am Dr. Dan Schultz, Director of the Office of Device Evaluation in the Center for Devices and Radiological Health at the FDA. I am pleased to speak today about FDA's implementation of Public Law 106-554 with respect to the labeling of condoms.

FDA has conducted an extensive literature and labeling review. Based on these reviews, we are developing a draft guidance document on condom labeling and proposed rule which would make the guidance a special control for condoms.

FDA regulates all medical devices in the United States, including condoms. Since 1987, FDA has issued a series of guidance documents that addresses specific elements of condom labeling related to protection against sexually transmitted diseases. The typical condom package contains a front panel on the external box that is referred to as the principal display panel. Current FDA guidance recommends that the display panel of the package for condoms include a statement regarding contraception and a statement on STD risk reduction, and that labeling emphasize the need for proper use.

Public Law 106-554, enacted in December 2000, directs the Secretary of HHS to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV. Although the interest of this hearing targets HPV, we complied with the law by exploring the labeling regarding other STDs as well.

To fully accomplish this task, we conducted a comprehensive systematic review of the published literature and other relevant information, and are now looking at how the results from this review might impact condom labeling. Our basic conclusions are as follows.

One, the protection a condom may provide against different STDs will vary depending on the transmission vectors of a particular STD, the specific infectivity of the virus or bacteria, and the biological mechanisms of progression from infection to disease. The law asks particularly about HPV infection, which can manifest as lesions, symptomatic or asymptomatic, on a man's penis, scrotum, a woman's vulva, cervix, or either's peri-anal areas. Because condoms do not cover all these areas, they may not provide the same protection as they do against STDs transmitted through bodily fluids like HIV or gonorrhea.

Two, condoms are highly effective against HIV and other STDs that are transmitted by genital secretions.

Three, studies on STDs characterized by genital ulcers, such as genital herpes and syphilis, are inconclusive as to whether condoms lower the risk of these diseases. We believe that the condom will provide some measure of protection when it covers the lesion or ulcer.

Four, clinical studies evaluating the relationship between condoms and HPV-related disease have not been consistent. However, even though the biologic mechanism has not been conclusively demonstrated, women whose partners use condoms seem to be at reduced risk for genital warts and cervical cancer compared to women whose partners do not use condoms. Therefore, there does appear to be a benefit from condom use for prevention of HPV-related disease.

As a result of these findings, CDRH has developed a regulatory plan to provide condom users with a consistent labeling message about STDs and the protection they should expect from condom use. FDA is preparing new guidance on condom labeling to address these issues. FDA anticipates proposing to

amend the classification regulations for condoms to make such labeling guidance a special control.

FDA is also committed to helping bring safe and effective technologies to the market, including new tests for the detection of HPV and improved methods of evaluating Pap tests. FDA is reviewing a number of investigational new drug applications for vaccines for the prevention of HPV infections, several of which are in advanced clinical development. In addition to efforts directed at HPV infection, treatment of cervical cancer is a very active field for clinical research, and several novel technologies are currently being evaluated for the treatment of this disease.

In conclusion, FDA is working to present a balanced view of condom performance, being careful neither to overstate effectiveness, nor to discourage use where it is appropriate.

Mr. Chairman, I want to reiterate that FDA is committed to monitoring closely the body of scientific evidence related to the degree in which male condoms offer any protection from HPV, HPV-related disease, and other STDs. We will continue to exercise our regulatory responsibilities to ensure accurate, clear, and understandable labeling in accordance with the best available science. I am happy to answer any questions that you may have.

[The prepared statement of Dr. Schultz follows:]

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Mr. Souder. Thank you.

I wanted to start with Dr. Thompson at CDC. Could you put the first chart back up again?

What do you estimate would be the number of women with abnormal Pap smears who require invasive treatment? Do you have any idea? You have high risk, general infections, the diagnosis, but do you have any idea of the number of women with abnormal Pap smears who require invasive treatment?

Dr. Thompson. Certainly. Virtually any woman with an

abnormal Pap smear certainly requires medical attention. How many of those will require invasive treatment versus observational treatment and other types of treatment I would not be able to speculate on, although there might be some knowledge of that with my colleagues from the National Cancer Institute.

Mr. Souder. Do you have any idea of that?

Dr. Trimble. Our surveillance methods do not capture pre-invasive disease very well, so our best sources cannot give you information.

Mr. Souder. Obviously, a cancer diagnosis is very severe. Part of the question is in how much we stress things related to HPV. In the category that I just was referring to, as far as invasive treatment, can that be painful, when somebody is doing that? In other words, is that something you would rather not have, presumably? In other words, we definitely don't want to get death, but what I am trying to say here, because this is a sexually transmitted disease that many people don't talk about or aren't familiar with, and we are looking at cervical cancer and you say, well, that is very extreme. But how hard we hit prevention is like are there a larger group of people even more than 12,000, and 4,000 who are exposed to invasive procedures that could in fact be painful, and we don't even know the number of them. So we don't even know the scope of the problem of what we have to prevent. Because we are not trying to just prevent cancer if in fact there are other painful things that could be avoided.

Dr. Thompson. I would not disagree with that at all. The important message that the chart is intended to convey is that two of those bars should not appear at all. We can prevent virtually all cervical cancer, and almost any cervical cancer death represents a failure of the system.

Mr. Souder. But the sole goal isn't to prevent cancer, because, while we want to prevent cancer, and obviously saving life is a primary, that would be, like I mentioned earlier, when we deal with a narcotics issue, is saying our sole goal is to prevent overdose deaths of heroin, as opposed to merely somebody who beats his wife, has other kinds of problems related to heroin. The problem with HPV is beyond just cervical cancer, it is a huge problem that we need to address, but it has somewhat of a difference here, how we focus on prevention as opposed to just treatment. Are those numbers just available or you just don't know them?

Dr. Trimble. We have no national surveillance system for capturing the number of Pap smears done each year in the United States. The data that Dr. Thompson cited is based on a telephone survey, so it was restricted, obviously, to women with telephones. So we don't know for sure the number of Pap smears done each year in the United States.

Mr. Souder. So you don't know how many abnormal either?

Dr. Trimble. We can estimate it based on some large samples. We know that, obviously for women who undergo a Pap smear, it is an uncomfortable procedure, as I think any woman in this room would be able to tell you. Women who are found to have an abnormal Pap smear then will undergo a repeat gynecological examination and colposcopy, which is uncomfortable, and can be painful if biopsies are taken. But I

can't tell you the number of, let us say, colposcopies done each year in the United States; there is no data source for that.

Mr. Souder. Obviously, I have had a number of friends who would have preferred not to have gone through that procedure; not necessarily related to HPV, but there are other things here other than just the final stages that we prefer to avoid if we can.

And given that premise, I also wanted to ask Dr. Thompson, how do you see the CDC, then, proceeding with HPV prevention, both to avoid the ones you have on the chart and also this probably much larger interim group that has precancerous lesions and other things that need to be treated?

Dr. Thompson. Well, we have a number of activities, some of which are already underway, and others will be guided now by some of the findings that we have made from this new report. I think as the report reflects, there is a need to educate providers more about some of the things that we have learned in this report. There is a need to educate the public to a greater degree about human papillomavirus, its relationship to cervical cancer, and the fact that it does require a variety of followup measures such as Pap smear screening; but, in addition, it can be prevented by certain behavioral decisions if the person chooses to make those decisions. And we are in the process of, in some cases, already reflecting in our documents for the public this new information. The other cases we are in the process now of gathering information about people's current knowledge so we can tailor messages to that current knowledge and so we can deliver it in ways that people will understand it and take it to heart.

Mr. Souder. Several members here referred, in a kind of a side comment way, to this, and so I wanted to clarify this question in a number of ways. The CDC HPV prevention report claimed that ``The use of condoms may reduce the risk of cervical cancer.'' The first part of this question is how many of the studies on HPV showed that there was a possible reduction in cervical cancer?

Dr. Thompson. There were three studies that were identified, among the published studies, that addressed this particular issue, and of those, if my recollection is correct, five identified a reduction in the risk of cervical cancer that was associated with consistent condom use, or at least with condom use as best it was measured by the survey. Of those five, two were statistically significant. So you have some statistically significant findings and a definite trend in all of the studies.

Mr. Souder. I missed what you said. There were five?

Dr. Thompson. I have been corrected, there were nine. And of those, seven showed positive results, but only two of those were statistically significant.

Mr. Souder. And when you say statistically significant, at what range, minimal significance or very statistically significant?

Dr. Thompson. The typical study value that we use, and I can't speak to these in particular, is at the 95 percent confidence level.

Mr. Souder. Ninety-five percent confidence level, which

would be 5 percent deviation. And then how significant was that 95 percent? In other words, you are confident that there was a statistical differential. Was it like a 1 percent difference or two? We heard earlier, when we were talking about the abstinence education, that it was statistically significant, and it was also a 30 percent differential between those who signed the pledge and not. So there are two parts. The statistical question is statistically significant; and then now that we have granted a statistically significant, was it a major, minor?

Dr. Thompson. How large was the difference itself?

Mr. Souder. Yes.

Dr. Thompson. In some cases the difference was small; in other cases the difference was relatively large and it showed a pretty substantial preventive impact.

Mr. Souder. OK, if you can give us maybe some followup data.

Dr. Thompson. If you would like the exact numbers, we can provide you those in followup.

Mr. Souder. I just need it for the record.

Of those who were found, what proportion of the women and girls are likely to require treatment for precancerous? You don't necessarily have that in those studies or do you have that?

Dr. Thompson. If you would clarify just a little bit what you are asking. Of the women in the studies how many required additional followup and treatment?

Mr. Souder. Yes.

Dr. Thompson. We don't have that information.

Mr. Souder. You don't have that. That is what we were talking about earlier. Is there any evidence that the women who use condoms do not develop cervical cancer?

Dr. Thompson. Yes. In the studies I just referred to, that was the end point that was being evaluated, cervical cancer.

Mr. Souder. And we have already addressed are there other threats to that.

I heard the discussion both in the written testimony and your verbal that you are working toward things, but I wanted to make sure that it is in the record. I ask it to Dr. Schultz. Is there currently an effective vaccine to prevent HPV infection or cervical cancer?

Dr. Schultz. Not to the best of my knowledge. But there may be other people who are more able to answer that question.

Mr. Souder. Dr. Trimble.

Dr. Trimble. The Merck Corp. has presented the results of a phase 3 randomized trial demonstrating that they were able to prevent infection with HPV-16. So that was a prophylactic trial targeted at one of the subtypes, the subtype which is the most common cause of cervical cancer.

Mr. Souder. So it is being developed, but it is not on the market.

Dr. Trimble. Right. The study has been published. They are currently studying a multivalent vaccine targeting additional three subtypes to HPV-16, but my understanding is nowhere in the world is there an HPV vaccine that is licensed and on the market.

Mr. Souder. How many subtypes are there?

Dr. Trimble. There are more than 100 subtypes of HPV.

Mr. Souder. So if this vaccine were effective, it would address, potentially, three of them.

Dr. Trimble. Four, actually. It is HPV-16 and 18, which are the most common cancer-causing viruses, as well as 6 and 11, which are most commonly associated with genital warts but not cancer.

Mr. Souder. Is there currently a microbicide that is available that would prevent transmission of HPV?

Dr. Trimble. Not to my knowledge.

Dr. Thompson. There is not one currently licensed for use.

Mr. Souder. Dr. Schultz, you agree with that?

Dr. Schultz. I would agree that there is nothing currently indicated for the prevention of that disease.

Mr. Souder. Do you believe condoms provide complete protection?

Dr. Schultz. No, I don't think they provide complete protection. I think a lot of people have addressed that question, and we would agree that they provide some protection, but not complete protection.

Mr. Souder. Do you agree with that, Dr. Trimble?

Dr. Trimble. Yes, we concur with the CDC's review of the issue.

Mr. Souder. I was a little confused, and I want to make sure because, Dr. Schultz, in your testimony you used ``appear'' and other things that were less decisive, and my understanding from your testimony, our current guidance recommends that the package insert for condoms contain the following statement: ``If used properly, latex condoms will help reduce the risk of transmission of HIV infection and many other sexually transmitted diseases, including'' and then you list about seven. Does that FDA guidance for condom labeling contradict the FDA scientific studies for this reason: that earlier you also said that some of the studies on STDs, I think it was the statement before that, were inconclusive? So if the studies are inconclusive, why would you list some of them as far as that it will help?

Dr. Schultz. I think the answer is that when those statements were formulated, we had a certain body of data to look at. I think what we have tried to do, again, over the last 3 years, along with our colleagues in the other agencies, is to examine that data more closely, which is why we are currently engaged in the effort that we are, to see about ways to improve that labeling. So I am not sure I can answer your question any better than that, but I think that we believe that the statements do have some value. We think that there are better ways and more informative ways to provide that information.

Mr. Souder. Because, at a minimum, anything beyond ``may'' seems a pretty big stretch at this point. Would you agree?

Dr. Schultz. I think that there are some areas where the word ``may'' is a stronger may, and then there are some areas where the word ``may'' is probably a weaker may. And, again, I think that is our goal, is to try to see if we can do a better job differentiating between those and providing, again, more informative information to the user.

Mr. Souder. I wanted to clarify for myself; I think Mr. Cummings isn't here right now. Did I understand you to say, Dr.

Thompson, that over 50 percent of the cervical cancer cases were minority?

Dr. Thompson. No. No, what I said, that in CDC's Breast and Cervical Cancer Screening Program, which is aimed primarily at under-insured and uninsured women, where you will find a lot of minorities, that approximately half the women served by that program are racial and ethnic minorities. We do not have figures, at least at hand, and I am not sure we have them at all, as to what percentage of the women found to have cervical cancer or cervical cancer precursors in that program are minorities and which are not. We can get those figures for you, but I would caution that since this is a safety net program, meant only to serve those women who have no other source of cervical cancer screening, that it is not going to reflect the larger U.S. population.

Mr. Souder. What would be interesting is if a percentage is 40 percent African-American is the rate of cervical cancer higher than 40 percent. In other words, do they have a rate proportionate to the number of people being served that are disproportionately hitting certain communities, because that would suggest where we have to do outreach targeting. Not that there wouldn't be a higher incidence in the population as a whole, but what is the incidence relation to their proportion of the people being screened?

Dr. Thompson. These figures do exist, and, if you would like, we will provide you with those.

Mr. Souder. I think that would be helpful for the committee.

Dr. Schultz, in the labeling, which is one of the reasons, if not the primary reason, we are having this hearing, because some of us have been concerned, why has it taken so long? It has been nearly 4 years since we first passed legislation in Congress; there have been lots of studies coming that we do all kinds of labeling things that we put on, and then if additional information comes, you might have to adjust it. But there seems to be a certain body of information that has been here and it has been 4 years since we passed the act. Why has this taken so long?

Dr. Schultz. I think that is a fair question, and I think that the best answer that I can give you, Mr. Chairman, is that we felt that this was a very important request and something that we needed to pay careful attention to. I think what we have heard today, and as is included in all of our testimony, there have been a number of studies, a number of meetings, a number of interactions that have occurred in those 3 years. We are certainly committed to looking at this and making the requisite changes, but we felt that our first responsibility was to attempt to gather the information and do it in a systemic and comprehensive way. So I would agree with your statement. I think that we have done that now, and our plans are to move ahead.

Mr. Souder. Well, I don't pretend to be as informed on these subjects as Dr. Coburn and Dr. Weldon, who were very active in this original piece of legislation, though I supported their efforts. One does 200 and one may do 4 Pap smears. I do zero. So I don't intend to be somebody who is expert on it, but I find it frustrating when people are dying

and many others are going through painful treatments, and others are getting diseases they are going to have the rest of their life, it takes 4 years to respond, when we have many other labeling type requests that also are very complicated, that required lots of research, that are very delicate, that are politically controversial, but seem to move faster than 4 years.

And one thing I would like for our record, you said there were meetings, there were different processes. We would like that for the record. We are an oversight committee. Part of our job is very specific. This committee is supposed to see that the laws of Congress are enforced by the executive branch. There was a time period that allowed the development of the studies, but that, to be generous, would be probably 2 years, not 4 years. And we want to see this move forward, but we would also like to see the evidence, as we have asked of the last administration, when we had lots of conflicts as a Republican. But also as a Republican administration, we want to see the evidence that the meetings took place, what they were, when they were, and why this process is taking so long.

Would any of you like to hear anything here? Because I am going to go vote and then we will be back, and I know Mr. Cummings is planning to be back too. Anything you would like to add?

With that, I am going to assume that we are done with this panel, and we will move to the panel. If Mr. Cummings, when he comes back, has any questions, if you could remain.

Just a second, let me find out how many votes there are before I ask you to do that.

I think, since he is not here, we are going to go ahead and dismiss, because we have three votes, so it will be quite a while. Thank you very much for coming. He will submit any written questions, Mr. Waxman and any of the other Members who do. Thank you for your time.

[Recess.]

Mr. Souder. The subcommittee now stands reconvened.

And if the third panel will come forth, Dr. Tom Coburn, a former Member of Congress, from Muskogee, OK; Dr. Freda Bush from Jackson, MS; Dr. John Cox from Santa Barbara, CA; Dr. Barbara Meeker from Traverse City, MI; Dr. Jonathan Zenilman from Baltimore, MD.

I am going to briefly recess the subcommittee again.

[Recess.]

Mr. Souder. The subcommittee is reconvened.

If you could each stand and raise your right hand.

[Witnesses sworn.]

Mr. Souder. Let the record show that each of the witnesses responded in the affirmative.

I thank you each for coming, and if I can again say for the record, in addition to Dr. Coburn from Muskogee, OK; Dr. Bush from Jackson, MS; Dr. Cox from Santa Barbara, CA; Dr. Meeker from Traverse City, MI; and Dr. Zenilman from Baltimore, MD. We thank each of you for coming and participating in our discussion today, and we will start with Dr. Coburn.

STATEMENTS OF TOM A. COBURN, M.D., MUSKOGEE, OK; FREDA BUSH, M.D., FACOG, JACKSON, MS; JOHN THOMAS COX, M.D., SANTA CLARA,

CA; MARGARET MEEKER, M.D., TRAVERSE CITY, MI; AND JONATHAN M. ZENILMAN, M.D., BALTIMORE, MD

Dr. Coburn. Mr. Chairman, thank you. I need to make some corrections. I am not a member of the American Academy of Otorhinolaryngology, but the American Academy of Otorhinolaryngolic Allergy. And I need to make that correction.

I am happy to be here. I am going to summarize my testimony and ask that my written testimony be made part of the record.

This is a disease that is very dear to my heart. I have delivered in excess of 3,500 babies, close to 4,000. I have handled every complication of sexually transmitted disease there can be, and there is no question that we have an uncontrolled epidemic in this country, worse now than when this bill was offered, and it is not being dealt with appropriately by the Government and the agencies in regard to that.

And I want to just describe an 18-year-old girl this last month who came in for treatment from me who has had one sexual partner. It hasn't been 10 or 15 years since she was exposed to this virus, she became sexually active at the age of 16. And through her testing and Pap smear, she ended up losing a good portion of her cervix to prevent her from having invasive cancer. That is not the end of the story, because what in fact it will do is decrease her likelihood of ever achieving a pregnancy, and, if she does achieve a pregnancy, increase the likelihood of pre-term delivery, which the average pre-term delivery in this country now costs us as a Nation about $200,000. So this disease is not without consequences.

I think it is also very important that we not just limit it to the sexually transmitted disease aspect of it, because there is a new study out just this year. Twenty to 25 percent of all head and neck cancers now are associated with this virus, can be directly associated with exposure of this virus. Rectal carcinoma, especially in the gay population, is 100 percent attributable to this virus. So there is tremendous costs associated with this virus that we need to look at and ask why the Government hasn't responded in the way it should in terms of prevention.

And I also interestingly note, and I think this is part of the culture that needs to be looked at, when we hear the CDC mentioned, we don't ever hear the complete name of the CDC mentioned anymore; it is the Center for Disease Control. We heard Dr. Thompson, who I have a great deal of respect for, but the fact is the Center for Disease Control is not their name. It is the Center for Disease Control and Prevention. And although they dropped the name of Prevention, in this case they dropped that aspect of the responsibility, because they failed miserably in terms of the prevention of this disease.

I also would make a couple comments outside of my written testimony. We heard several times today about statistically significant reduction in cancer of the cervix associated with condoms. There are 20 studies in that. Two may show, and the word is ``may''; it is not does, it is not ``is,'' it is not ``will'', it is may show a reduction. There are 15 that statistically say there is no reduction in cervical cancer. So it is important to have a balanced look. There are two that may show a reduction.

The other thing that I would say is what Congresswoman Norton had to say is right on. We need access for the women in this country to make sure they are screened. There is no question about that. And there is no question that the minority population has the greatest risk for not being screened. Of the two cancers of the cervix in my practice in the last 2 years who have gone on to die were both minority women who presented late with an advanced stage of the disease.

Finally, I would make a point that the CDC did not address. There is over 1.350 million procedures done every year in this country for cervical dysplasia, and that ranges all the way from just doing a simple microscopic exam with biopsies of the uterine cervix, to cryotherapy, to laser surgery, to what we call leap electrical excision, to hysterectomy. And those aren't even counted in the numbers that the CDC are looking at. So the minimum we are spending, the minimum we are spending in this country on this disease on a gynecological aspect is $3 billion. That doesn't have anything to do with all the late stage carcinoma of the vulva, which is out there that CDC isn't following. Nobody is looking at a young lady who gets treated by HPV and then 35 years later ends up with a carcinoma of the vulva, of the reproductive system; and nobody has gone back and nobody has looked forward to see what that cost is. So if you look at the overall cost of what we are paying in terms of health care dollars for the lack of prevention for HPV, what we see is a cost greater than what HIV is costing this Nation; and we ought to talk about it frankly.

And then the final point that I would make, as my time is just about out, is our young people aren't stupid. They may make immature decisions, they may make wrong decisions, but to say we should not give them every bit of information about this disease, and to say that a condom shouldn't be labeled appropriately to warn them that this will not protect them, and the fact that a condom, in the best hands of an adolescent, fails about 13 to 20 percent of the time for pregnancy, so it is not a cure-all that we hear so blatantly stated; and in terms of sexually transmitted disease it is even less than that, of many of the other diseases.

So I would like to see the committee look at the total aspect of this disease, also to follow the public law that I authored before I left Congress, and to hold accountable the CDC and the FDA. To think that the FDA may not, and I thought it was very peculiar. I thought may meant may, I didn't know may meant strong or soft or weak. I thought may meant may. And the fact is condoms do not offer significant protection against this virus, and the packaging ought to label it, because our children have a right to know. If they want to make a bad decision, they will. And I routinely advise patients in my practice that if they are going to be sexually active, and if they are going to be outside of monogamous relationships, they ought to always use a condom. I am not anti-condom, but I am pro-truth and pro-science. And this isn't a bias, this is inter-
rupting a health pattern that costs us dearly, impacts lives tremendously, and the social and emotional costs of this disease cannot be measured.

And with that I thank you.

[The prepared statement of Dr. Coburn follows:]
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Mr. Souder. Thank you very much.
Dr. Bush.

Dr. Bush. Thank you, Mr. Chairman, for the opportunity to speak here today to this very important issue. I am Dr. Freda McKissick Bush from Jackson, MS. I have been practicing obstetrics and gynecology for the last 21 years, and I have been in women's health for about 35 years helping women to have positive childbirth experiences, because I think it is great to be a woman, but also helping them make good choices for their gynecologic health.

Through the years, the hidden epidemic of human papillomavirus [HPV], has been a challenge to them achieving that ideal. HPV is the most prevalent of all viral sexually transmitted infections, as we have heard this morning, and it is estimated that 5.5 million women are infected by HPV every year in the United States, 3.5 million have abnormal Pap smears; 13,400 are diagnosed with cervical cancer, and 4,100 die.

Of the more than 100 HPV strains identified, around 35 can infect the human genital tract. Infection with benign strains that do not cause cancer may lead to genital warts, which may be associated with itching, burning, or pain. In contrast, most infections with cancer-causing strains may have no symptoms at all. Unlike non-sexually transmitted viral infections such as the common cold, influenza, or measles, that only last a week or two, HPV infections can last for months, and occasionally for years.

Recent estimates indicate that 50 to 75 percent of sexually active adults are HPV-positive. In general, that puts sexually active people at risk for HPV. This includes age at onset of sexual activity, at least age, less than 16 years; multiple sexual partners; sex with partners who engage in high-risk sexual behavior; adolescent and young adult females are biologically more susceptible to HPV disease because their cervix has not yet matured. So you have younger people getting infected and suffering greater consequences because of the immaturity of their bodies.

The incubation period between HPV infection and the development of genital warts ranges from 30 days to 9 months. These changes resulting from cancer-causing strains are usually

not visible to the naked eye. Once a person is infected, the virus persists for an average of 8 months. Approximately 10 to 12 percent of women will have persistent infections. The persistence of infection has been identified as a significant risk factor for the development of cervical dysplasia and cancer.

With current Pap smear screening technology, it is possible to sort abnormal specimens into low-and high-risk categories. Patients with high-risk types require microscopic evaluation of the cervix to identify the abnormal areas so that cervical biopsies can be obtained for pathologic evaluation.

In the United States, more than 50 million Pap smears are evaluated annually. The question was asked earlier what does this translate into as far as pre-cancerous lesions. According to the American Cancer Society, 1.2 million Pap smears have low-grade squamous interepithelial lesions; 300,000 have high-grade lesions. Sadly, 13,400 cases of cancer are diagnosed.

Approximately two-thirds of males whose female sexual partners are diagnosed with cervical dysplasia have microscopic HPV lesions of the penis. Infection of the penis or anus with high-risk HPV types predisposes these men to cancer of those organs.

Because HPV is a viral infection, no curative treatment is available. In 2000, a national panel was convened by NIH to investigate condom effectiveness. This panel found that condoms do not provide any protection for HPV infection in females, although it may reduce the risk for HPV-associated diseases. Because genital warts and asymptomatic HPV infection may be outside the area covered by a condom, consistent and correct condom use leaves a significant chance for transmitting these and other sexual diseases.

Obviously, the best way to prevent transmission of any sexually transmitted infection is to abstain from sexual intercourse outside a long-term mutually monogamous relationship such as marriage. Ad Health, the nationwide adolescent health study, found that the best deterrent to sexual activity among adolescents involved parental influence, moral and religious training, community influences, and appropriate peer influences.

In conclusion, HPV is a preventable disease. You must initiate methods to track the incidence and prevalence of disease. We must take steps to stop the alarming increase in this disease among teens and young adults. We must stop promoting methods that are known to have high failure rates in preventing HPV transmission, notably the condom, and be honest in informing young people about this fact. We must continue to emphasize highly effective methods of prevention, namely abstinence, whenever possible.

Thank you, again, for the opportunity to continue to promote health.

Mr. Souder. Thank you. And we will make sure that NIH, FDA, and CDC get your number, since they didn't appear to have those numbers at a congressional hearing meant to discuss that subject, which was a tad frustrating.

Dr. Bush. Yes, sir.

Mr. Souder. Dr. Cox.

Dr. Cox. My name is Tom Cox. I would like to thank you for

having me here today. I have been a gynecologist for 30 years. I am the director of the Women's Clinic at the University of California-Santa Barbara. For the last 16 years my primary interest has been in studies on the natural history of HPV and cervical cancer, and on the best options of prevention of cervical cancer, including writing national guidelines for both primary screen and management.

I had the privilege of testifying before the House Subcommittee on Health and the Environment on HPV in 1999, and at that time I mentioned the tremendous progress this country has made in reducing cervical cancer rates as a result of Pap screening. In 1949, the year that the Pap screening was introduced to this country, the 2004 equivalent of 50,000 cases of cervical cancer occurred. This rate is 12,200 this last year and is solely, but steadily, declining.

Since 1999, there has been a real ``sea change'' in cervical cancer screening recommendations and in management of women with abnormal Pap tests. New recommendations have been issued that focus on detection of the cause of cervical cancer, and we all know that to be HPV, and not solely on the often subjective cervical cellular changes in cytology. Improved screening and improved management of abnormal Pap tests, and the promise of an effective vaccine against the most important of the oncogenic HPV types are moving us toward the eventual elimination of cervical cancer. In the near term, better targeting of high-risk populations could translate into further progress in reducing cervical cancer.

By high-risk populations, I am referring particularly to the majority of women who get cervical cancer who have either never had a Pap test or have had one or more Paps, but have not had them at recommended intervals. A substantial commitment to understanding the reasons for failure to attend screening and facilitation of access to health services is necessary in order to overcome these barriers. As far as I am concerned, this is where our focus today should be, because this is something we can truly do something about.

Cervical cancer not infrequently strikes women of late childbearing age, disrupting families and society much more than many other cancers that occur with highest frequency in the elderly. The fact that cervical cancer can be prevented in most circumstances makes these deaths especially tragic. Wise investment by Government in a program of cervical cancer prevention is, therefore, both morally right and economically sound.

As we have heard repeatedly today, infection with HPV does not mean a woman will eventually get cancer. The reality is that the vast majority of sexually active Americans will be infected with HPV at some point in their lives, but only a small proportion of women infected with HPV will see it progress to cervical cancer. Most commonly, the immune system suppresses or eliminates HPV, usually within 6 to 24 months, and although HPV must be present for cervical cancer to develop, the converse is not true. The good news is that cervical cancer is nearly entirely preventable because the progression from pre-cancer to cancer typically takes years or even decades, during which time persistent infections leading to pre-cancer can be detected by Pap screening or HPV testing,

and subsequently treated.

So given the complexities of the HPV-cervical cancer link, what are the appropriate public health messages? I would argue that policymakers and public health practitioners have an obligation to be both realistic and pragmatic. The median age for marriage in the United States continues to rise for both men and women. By 2000, the median age for first marriage was 25 years for women and 27 years for men. The median age of puberty is 13. Throughout history, virginity, at least for women, until marriage has been secured primarily by either very early marriage of women, soon after puberty, or by sequestering women in strictly controlled separation of sexes until marriage. Neither option would be acceptable in this country; hence, 90 percent of Americans engage in sex prior to marriage. So although abstinence messages for young people make good sense, abstinence until marriage as the sole message is irresponsible.

I would urge those individuals influential in making public policy to avoid fear-based messages that overstate the risk of HPV and understate the protection provided by condoms, particularly for other STDs, particularly for HIV. Disparaging condoms threatens to undermine the tremendous progress that we have made in lowering teen pregnancy rates and in reducing the risk of transmission of far deadlier STDs such as HIV. Instead, the most helpful public health message for the prevention of cervical cancer is to encourage women to get appropriate screening and recommended followup care.

Again, thank you for the opportunity to address these issues. I firmly believe that the war against HPV and cervical cancer can and will be won in my lifetime, but it will not be won by hyperbole, but rather by providing the best protective cervical screening available for all women and by providing HPV vaccines to all children once these vaccines become available.

My written testimony contains additional details. I would be pleased to answer any questions that you may have.

[The prepared statement of Dr. Cox follows:]

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Mr. Souder. Thank you.

Dr. Meeker.

Dr. Meeker. Thank you.

My name is Meg Meeker, and I am a physician of child and adolescent medicine. I have been practicing adolescent medicine in Michigan for about 20 years. So I represent a population of patients very dear to my heart, that is the children in America.

I am grateful to have the opportunity to speak to you on behalf of my own patients and the 35 million teenagers across the United States. For about 20 years I have taken care of thousands of teens, I have authored two books on teen health issues, and currently speak across the country on teen health issues. I am a fellow of the American Academy of Pediatrics and certified by the American Board of Pediatrics.

Ladies and gentlemen, the epidemic of sexually transmitted diseases among our youth in the United States today is sobering and poorly recognized by the public at large. This year, in 2004, 10 million teenagers and young adults under the age of 25 will contract a new sexually transmitted disease. That translates into approximately 8,000 teenagers in the United States every day contracting a new sexually transmitted disease. Human papillomavirus, as you are hearing, outnumbers all other sexually transmitted infections among our youth and costs our country billions of dollars yearly because it wreaks havoc in the genital tracks of, may I say it again, teen girls and very young women.

We are here to discuss prevention of HPV infections and cervical cancer. If I might for a moment, let me permit you behind closed doors that physicians like myself see every single day. Fifteen years ago I rarely saw abnormal Pap smears in young girls; 10 years I personally witnessed a dramatic rise in the frequency of abnormal Pap smears among my own patient population of young teenage girls, many of those as young as 13; and 4 years ago I had to break the news to one of my young patients, we will call her Amy, just before her 14th birthday that, no, she didn't have full-blown cervical cancer, she had the milder form of severe dysplasia, but needed cervical surgery nonetheless. She had her surgery, 3 months afterwards returned to my practice with signs of very serious depression. The morbidity, not just the mortality, but the morbidity of this disease among young women is tremendous.

Cervical cancer is a young women's disease and deserves our strongest efforts at real and aggressive prevention, not just medical management of the cure, that giving an increased number of Pap smears to young girls will afford. That is very important, but that is medical management of a disease, it is not a primary strategy of prevention of the cervical cancer. So what can we do to truly prevent human papillomavirus infections and cervical cancer in our young women in America?

We could more aggressively train our children to use condoms during sexual intercourse. There are, however, serious drawbacks to this approach. The scientific data, and may I say from the National Institutes of Health condom effectiveness report shows that there is insufficient evidence of any risk reduction for sexual transmission of human papillomavirus even with 100 percent condom use, which I might add, among youth doesn't happen. The primary reason for this, and no one has

discussed this, is that HPV is not transmitted like HIV, which is transmitted through bodily fluids; it is transmitted from skin to skin. And even the best condom available out there only covers a certain portion of the skin. So unless we make condoms a lot larger, it is very difficult, with condoms alone, to prevent the transmission of the cervical cancer-causing agent human papillomavirus.

Second, we could increase screening for cervical cancer. While increased screening is very important, and I might add does not take place in the most at-risk population, and that is children, whom I represent, and I am one of the few pediatricians who does gynecology in my practice, I might add, while that is very important, it is a secondary, not a primary strategy for prevention of the disease. At the time of screening, many women may have already become infected and show signs of dysplasia or even more advanced cancer. Screening detects HPV infections, it does not prevent them from occurring. The only way to prevent infections and subsequent sequela in our young girls is to teach them the only way to avoid infection, as Dr. Gerberding's report shows from the CDC, is to abstain from sexual activity during the teen years, the high-risk years.

Distinguished Members of Congress, we are indeed living in schizophrenic times. Every day our children are bombarded with sexual messages from the entertainment industries and multimillion dollar corporations aggressively marketing sex to them from the age of about 8 years old on. I believe, personally, that these messages have a profound effect on their sexual behavior. Teens have begun sexual activity at younger and younger ages, and have dramatically increased the number of sexual partners in recent years. They come to their physician's offices and then we, and I speak for the thousands of doctors who, across the country, work fervently to deflect the damage done to their young bodies, just to their bodies from sexual activity. Daily we ``mop up the messes,'' if you will, of too much sex too soon.

We have become overwhelmed and discouraged because the bottom line is that sexual activity among our youth is out of control. The best medical data on sexually transmitted infections in teens teaches us that there is two successful ways to drive down the STD epidemic of teens in our country: One, delay the onset of sexual debut and two, drive down the numbers of sexual partners.

If we commit to help our young women accomplish these two goals, then we offer the best medical care available to prevent cervical cancer. We physicians cannot fight the uphill battle of rising HPV infections in younger women and out-of-control teen sexual activity alone; we need your help in sending clear and loud messages to our communities and to our youth that sexual activity in teenagers, with or without condoms, is very high-risk behavior.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Meeker follows:]

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Mr. Souder. Thank you.

Dr. Zenilman, you will be our cleanup hitter.

Dr. Zenilman. With a name starting in Z, I am used to being at the end.

Mr. Souder. I can imagine. Except for those rare days when they reversed the order, those wonderful days.

Dr. Zenilman. Good afternoon. Thank you for having me. My name is Jonathan Zenilman. I am professor of medicine at the Johns Hopkins University School of Medicine and chief of infectious diseases at Johns Hopkins Bayview Medical Center. My area of research and clinical expertise for the past 18 years has been in sexually transmitted infections. I am also the president of the American STD Association, representing 450 academic and public health researchers in this area; and also I am a practicing physician and take care of patients with reproductive tract infections at the Baltimore City Health Department and in my own academic practice at Bayview Medical Center.

More important, I am the proud father of three teenagers, one of whom, Aliza Zenilman, with her friend, Mandy Millman, is here with us today in the second row sitting behind me. I thank the committee for extending your warm welcome to her and her friend today.

I address this committee as a private individual, a physician, as a public health practitioner, and as a father who gives patients the advice that I give my own children.

We are hearing and have heard today that HPV infection is almost always asymptomatic and is extremely common. I will therefore limit my comments to highlight issues which have not been already addressed by the previous witnesses.

Some strains, as you know, of HPV are associated with the development of cancer. Recent studies we have performed in a Hopkins suburban clinic in Baltimore, supported by the CDC Sentinel Surveillance Grant previously mentioned, found that the proportion of women infected with high-risk HPV types is 14 percent higher in persons of color and persons with HIV or those at risk for other reproductive tract infections. Extrapolating from these and other data, I would estimate that approximately 1 in 6 to 7 individuals sitting in this room is currently infected with a high-risk HPV type. Let me say, however, and emphasize that Pap smears, which have already been previously testified to as the major control strategy, are actually a screening test for a cancer that is caused by a sexually transmitted viral infection.

In terms of primary prevention of HPV and other STDs, we try to give our adolescents and young adults a moral compass that will help them in making informed choices regarding their sexual health. A British colleague of mine once said, ``The most effective contraceptive is ambition,'' which requires us as a Nation to provide an environment of educational and economic opportunity, as well as positive recreational outlets for our young people.

Effective prevention of risky sexual behavior and their consequences, teenage pregnancy and sexually transmitted infections, requires two critical components: one, accurate based science-based information on reproductive health and prevention of infection and pregnancy, and two, a social peer

and family environment that promotes responsible decisionmaking, allowing teens to make an informed choice. Unfortunately, many teenagers do not have both of those criteria.

Delaying sexual intercourse is a public health message that I and all reproductive health professionals support, in tandem with counseling on responsible sexual behavior. An abstinence-only approach which excludes safer sex messages and includes messages that emphasize intercourse only within the context of marriage, is therefore clearly out of touch with the realities and practices of the vast majority of Americans. We are performing a disservice by focusing only an abstinence-only approach.

Condoms are highly effective in preventing sexually transmitted infections, including genital herpes and HIV infection. In the latter case, condom use is life-saving. In communities where condom use has been universally adopted and supported, dramatic and striking decreases in overall STD and HIV infection rates have been observed.

As a parent, I want public policies that are reality-based and provide the resources necessary for my children, along with my patients, to protect themselves. I want them to have access to medically accurate sexuality education. I want to see support for research efforts to develop and make vaccines and other prevention interventions.

Unfortunately, the debate on human sexuality, sexual behavior, and STDs is all too often framed in an absolutist stark context in which only simplistic solutions are framed to address inherently complex behavioral and social questions. This is not a new phenomenon. More than 60 years ago, Dr. Thomas Turner was a colonel in the U.S. Army during World War II and was in charge of venereal disease control effort for 14 million servicemen and women. He was later to serve as dean of the Johns Hopkins Medical School and died in 2002 at the age of 100. I had the privilege of getting to know Dr. Turner in the late years of his life.

As a sidebar, if you are a venereologist, you may live to be a long age.

During World War II, Dr. Turner and the Army were faced with the same dilemma we now see facing as this Nation develops policies and practices. As only he could, he described the difficulty in providing expedient and simplistic approaches. ``If a soldier remained continent, he would not acquire venereal disease. Many did remain continent, but no one in his right mind would expect this of a high percentage of men in their most vigorous and disorganized years. The first paradox, therefore, was preaching continence as an official doctrine, while simultaneously providing instructions and facilities for prevention of disease during and after sexual intercourse. We were repeatedly impaled on the horns of this dilemma. Some worthy folk urged a firm stand on a high moral plane; otherwise accused us of crass hypocrisy.''

Dr. Turner held steadfast in pursuing a pragmatic solution, and I implore you to follow Dr. Turner's lead in approaching today's STD problem. Thank you.

[The prepared statement of Dr. Zenilman follows:]

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Mr. Souder. One of the things I wanted to clear up at the beginning, I understood from our earlier panel, and I thought I heard at least alluded to by several of you, that up to 80 percent of Americans would get HPV sometime during their lifetime. Does everybody agree with that?

[Panel members indicate in the affirmative.]

Mr. Souder. Then why I was confused, Dr. Cox, is you said we shouldn't be alarmists. Eighty percent is a pretty high number.

Dr. Cox. Well, I didn't say that we shouldn't be alarmed. What I was saying is that we shouldn't overstate the risk.

Mr. Souder. But 80 percent? So you are not talking about overstating the risk of people getting HPV.

Dr. Cox. Overstating the risk of what you get from HPV.

Mr. Souder. The cancer part.

Dr. Cox. Right. That is correct.

Mr. Souder. But not invasive procedures?

Dr. Cox. I think we all have the same goals, and I would agree with Dr. Meeker here, that we all want to try to encourage young people to delay intercourse as long as they possibly can, and give them the health reasons for that. There is no question that is a real positive. We all foster that. The only difference amongst the four or five of us up at this table is the fact that some of us believe that only abstinence should be taught in school, and that would protect individuals from starting intercourse too early, and others of us feel that you have to be more balanced.

Mr. Souder. I don't believe that. I believe that is an inaccurate statement, for the record. You have broader disagreements than that, and I am going to explore some of those disagreements.

Dr. Cox. OK.

Mr. Souder. I agree that is one of the differences of opinions.

First, some have claimed that you can provide medically accurate labels on condoms, and that this would discourage condom use. Do you believe that condom use would be less if things were accurately labeled?

Dr. Coburn, do you believe if we put a label on that gave accurate information, which, by the way, could be argued by putting accurate information as a doctor, any of you want to do this, we face this problem. Let me ask a general labeling question. You were both a doctor and a legislator, and on the Energy and Commerce Health Committee. When we said that certain things that address diseases or health problems, when they run advertising, they have to have warnings on TV, and that they have to accurately address what the product does, what was the discussion about let us don't accurately label versus they

might not use that drug? How does this process work, and how do we balance that as legislators? And you both being a legislator and a doctor, could you talk about how we sort this through? Does accurate labeling discourage usage? And what if somebody could have used that medication, but we said it might have side benefits, so they don't use the medication?

Dr. Coburn. Well, let me preface it first. Anybody that is going to be sexually active in our society today who is going to be sexually active, ought to wear a condom. OK? Period. Because it will reduce the risk. The difference is saying that we don't want to tell people the truth because if we give them too much information they might make a bad choice undermines the whole basis under which we run our society. And if you carry that a little further, the logical conclusion is that if you tell everybody to wear a condom and don't tell them anything, then why would they ever come get a Pap smear, because a condom protects them? So you can't be on both sides of the logical argument.

The fact is we need as a policy, a national policy, that we ought to be truthful about the risks of STDs. We shouldn't be alarmists, but we should be truthful, and we should trust our children to make good choices, and we ought to have leadership. And what we don't have in this country today is leadership on this issue. You have not heard the surgeon general talk about the No. 1 STD in this country and the fact that it relates to at least 1.350 million procedures every year, that it costs at least $3 billion, and that we could make a difference on. And it is not about condoms or non-condoms; it is not about abstinence versus non-abstinence. The fact is that we ought to teach our kids to give them the best medical advice, and then if they choose to not use that best medical advice, if they use a device that will help lower their risk, then it ought to be labeled accurately.

And I would take exception. I am head of the President's Advisory Commission on HIV/AIDS. We have not lowered HIV infection in this country. We have as many or more new HIV infections in this country as we had 10 years ago. We have failed miserably. We have spent billions of dollars on this message. We have a higher rate of STDs today than we have ever had; we have a higher rate of HIV infection than we have had; we are spending more to treat. So we have sent the message, and if we applied the same thing to cigarette smokers, well, our society is going to smoke cigarettes and we can't change the culture, leadership is about changing the culture, because it will pay us big dividends both in health and social and emotional aspects of how we interrelate to each other.

So I think we ought to see a label that is accurate. It shouldn't be inflammatory, it should just be scientifically accurate, and there shouldn't be anything wrong with it. But it ought to be accurate not just about HPV, it ought to be accurate about chlamydia, because the studies on chlamydia aren't very good, when we are wanting to protect young women from chlamydia.

Mr. Souder. Is there anybody here who opposes more accurate labeling on the condoms?

Dr. Cox. My basic concern about labeling the condom as not being an adequate protection from HPV is just you have to cram

everything on a condom label in such a small area. I am very concerned about the mixed messages that individuals might get because HPV sounds like HIV, like HSV, like HBV. All these other STDs sound similar, so I am concerned that there might be decreased use on that basis. I would rather see a label that said something like properly used condoms significantly protect against some, but not all, STDs. I just get concerned about the message when you try to put one single STD on there, and how it might be mixed up with others.

Mr. Souder. Do you believe that other warnings that we have on other medicines and medications also can discourage usage, and would you favor not labeling them because people might not use them?

Dr. Cox. Personally, I don't quite make the connection between those issues, but, yes, I know some people don't take medicines because they worry about the warnings we put out on medicines.

Mr. Souder. So would you recommend we label them less accurately?

Dr. Cox. No, I am not recommending that at all. I am just saying that I am concerned about the mixed messages individuals may get not his.

Mr. Souder. But, see, the double standard, and this is what bothers some of us. We are not arguing about whether we should fund Pap smears, we are not arguing about whether we shouldn't do more treatment questions, look at at-risk populations. We have a specific piece of legislation that says accurate labeling, and there are several parts of this that we are going to pursue, but, first, most of the Democratic Members who were here earlier seem to support accurate labeling. Now, we can argue what is accurate, but that in the accurate labeling problem here is why we should have warnings. And as Dr. Coburn just mentioned the Surgeon General not speaking about this, what some of us are wondering, and this is our challenge, is are people not speaking up about this problem because they have other agendas? Are they blocking warning labels here, where we seem to be putting warning labels on all kinds of things, because they have other agendas and they are uncomfortable with what seems to be the most effective things?

For example, we have heard multiple times, I know I have raised other types of issues, but in smoking we don't give Dr. Zenilman used the word ``inherently simplistic messages.'' Our messages against smoking are inherently simplistic, and the billboards that we see up are very simplistic. Let me just say flat out the data under ``Just Say No'' were more effective than they were when we gave more inherently complicated messages. We can argue whether there were other things going on, but the plain fact of the matter is inherently simplistic messages move a certain percentage of the population and that, in fact other patterns, also to take the quote from Dr. Turner, at that time the military was also providing cigarettes to people because they believed people couldn't have their behavior changed.

In fact, behavior changed. And if there is something like high-risk sexual behavior, that is causing the amount of problems that we have in the United States, whether it is HPV, HIV and other things, why wouldn't our primary aggressive

prevention strategy be abstention. And then acknowledge, as Dr. Coburn just did, look, if you are going to engage in high-risk behavior, make sure it is absolutely clear that it is high-risk behavior, it shouldn't be followed. But if you do, here is what you have to do, and then if you have done that high-risk behavior, we need to treat you and take care of you.

I don't understand where the resistance is to acknowledge that it is aggressively high-risk behavior and needs to be reversed. I don't understand the resistance to this. To just say, oh, well, it is happening; therefore, we have to not be aggressive in our response. We are aggressive on date rape. It is happening all the time; it is probably increasing. But we don't not speak out against date rape. We have sexual harassment as a huge problem in our society, possibly increasing, but we don't not speak out against it because it seems to be something many people do. I don't understand the fatalism that I am hearing.

Dr. Zenilman. You asked, actually, quite a complex question, so I will try to distill it down.

I don't think we can compare date rape or sexual harassment to consensual sexual intercourse between teenagers or young adults.

Mr. Souder. But the consequences of teen pregnancy, out of wedlock, not finishing school, teen suicides, lack of stability in marriage over long-term, kids having multiple higher rates of different problems, sexually transmitted diseases. How can you say that there aren't those extreme consequences to out-of-wedlock pregnancy in our society, and sexual activity, which is directly related to that?

Dr. Zenilman. In reference to the specific, I think that is why this is actually an inherently complex issue. First of all, in the 1940's, the Army did not recognize that cigarettes were a problem. The military and the VA have taken cigarettes out of at least onsite consumption or purchase, which was actually a direct issue.

I would argue that this is a much more complex behavioral issue than cigarette smoking. And, furthermore, I am in agreement with you. I am in agreement with the other members of the panel that our major objective should be to delay onset of sexual intercourse. I think you have heard unanimity from all of the witnesses on this specific issue.

Mr. Souder. That should be our primary prevention strategy?

Dr. Zenilman. I think that should be the major focus.

Mr. Souder. It should be the major focus, the primary preventions strategy?

Dr. Zenilman. It should be the major goal in adolescent sexual health. But on the other hand, and you may call it fatalistic, I may call it realistic, recognizing that most people, the vast majority of Americans are not going to follow that advice. So, therefore, in the context of a public health reality, our objective is to minimize the risk to individuals who are engaging in sexual behavior.

Now, I would also argue that I don't like the context of intercourse in teenagers having consensual intercourse or adults having sexual intercourse is not the same as a date rape or sexual harassment. The latter has a lot more of the consequences that you mentioned previously.

Mr. Souder. I don't think this data backs that statement up. I believe they are awful and I have worked with them, but you are not going to argue here that out-of-wedlock pregnancy and related things are less damaging overall to a life's career than somebody who has been sexually harassed, which, by the way, may also occur in the teen pregnancy and the out-of-wedlock or non-married sexual activity.

Dr. Zenilman. A consensual adult who is actually having sexual relations and is properly informed will be contracepting.

Mr. Souder. This isn't really a debate, and I am sorry I got us off into that. We have a substantial disagreement.

Let me go next to the female physicians on our panel. Some have downplayed the threat of HPV infection by suggesting routine tests and, if necessary, treatment can prevent the development of cervical cancer. Can you describe the treatment that a woman would undergo for abnormal cell changes? Dr. Bush, maybe you can start with this, because you referred to this high number. Is cervical cancer or HPV related dysplasia easily treated? And what are some of the side effects of the treatment?

Dr. Bush. Basically, we encourage women, once they have initiated sexual activity, to begin getting routine annual Pap smears. The reason we are screening is because HPV is the leading cause of cervical cancer, and it can be detected with the Pap smear. So as someone said, HPV causes cervical cancer and it is a preventable disease.

When the women has an abnormal Pap smear, they can be graded into high grade or in low grade or atypia. When a low-grade atypia is found, we may simply repeat the Pap smear because a significant number will spontaneously, because of their immune system, get rid of it. But with persistence, and that is the problem, 10 to 12 percent of people will have persistent infection and it will not go away, and that is associated with the high incidence of cervical cancer. If it is a high-grade lesion, which goes from moderate to severe dysplasia to carcinoma incite two, they are more likely to progress to cancer, and often it does not take 10 to 15 years. As Dr. Coburn mentioned someone in his practice, I could mention someone in my practice who actually initiated sex after age 16, and at 19, very recently, I had to do a leap procedure because of persistent infection.

What happens is we do a colposcopy, which takes a microscope, looks at the cells, we biopsy and take a chunk of the tissue, send it to the lab, let them tell us if the Pap smear was accurate or how far it has; sometimes it is less, sometimes more. With persistent of the infection confirmed by the biopsy results, then you have to remove those cells so that they do not progress. Removing means cryosurgery to kill them, it means an electrical surgical loop procedure to remove the cells, it may mean colonization, which is an outpatient surgical procedure surgical procedure, and it does cause pain; you have to give anesthesia, analgesia for the removal of that tissue, it means that you put the lady at risk whether she becomes pregnant, when she becomes pregnant in the future, not only the risk of premature delivery, but also perhaps stenotic cervix, that she would have to have cesarian section, that her

cervix hadn't opened.

To make a long answer short, there is significant morbidity that is associated with an abnormal Pap smear. Persistence of the infection does progress to cervical cancer, and we are talking about 10 to 12 percent of people that have persistence.

Mr. Souder. Dr. Meeker, the New York Times, you heard us refer in the first panel when you were here, to this study that we have been kicking around among the members, that a majority of high school teens are virgins, according to the latest CDC data. This is a reversal from a decade ago. As a pediatrician, do you think abstinence is a realistic approach to trying to stop STDs among kids?

Dr. Meeker. Well, I know it is, because I want to remind everybody that the epidemic of diseases that we are seeing amongst our youth now weren't here 40, 50, 60, 70 years ago, even as recently as 30 years ago. And I would ask have we fundamentally, as human beings, changed? No. I mean, our physiology is the same. What has changed is the direct marketing to our younger and younger children sexually promiscuous advertisements and so on and so forth.

What also has changed is the increase in the number of sexual partners that teenagers have and the earlier onset of sexual activity, and that is what has increased the number of STDs. So children, teenagers, the majority of teenagers will take their cues from significant adults in their life. The Ad Health study shows that. If it is communicated to teenagers, expectations about sexual activity from an authority figure in their life, teenager or a parent, the majority of teenagers will follow that and they will abstain from sexual activity.

I think there are some very significant and very serious misunderstandings about abstinence-only education, if I might. There is a sense that those promoting abstinence-only education are trying to withhold information. That is absolutely not true. What we are trying to do is just teach kids what the very real risks are to condom use. No one in this panel would tell a kid not to use a condom, and we are all willing to say that there is a role in condom use, but our money needs to be and our efforts need to be in teaching kids about abstinence. Everybody here is saying that we need to communicate messages to our kids that will change their behavior, so some say we need to encourage them to use condoms more frequently and better, or our other alternative is to teach them not to be sexually active. Either way, all of us are asking our kids to change their behavior.

We know how well teaching teens about condoms has worked; we have the data. And the data shows us that condom use has increased; young kids will use condoms the first, second, third time, but after that, as their age increases, condom use decreases. So we know what the data shows, and that basically asking them to change their behavior toward increased condom use has not worked. And in the midst of increased condom use, the STD rates, HPV too, have risen. So now I will say why not try the second approach? Why do we not then say what we need to do is put our time and our energy and our money into programs that will teach kids to delay the onset of sexual activity, which is abstinence?

Dr. Cox. Chairman Souder, I might add there is a study that

was just released this week out of England, where they went to a full-blown condom message, and what they have is a disaster on their hand as they go back and measure, in terms of increased teen pregnancies, increased STDs, and increased onset of early sexual debut. And what they are doing, the government in England now is reassessing whether that program is right, because what they did was actually increased sexual activity. And I am not saying that all condom messages do that, and I would not say that, but the British have decided that maybe they went down the road the wrong way, because they actually have marked increases in all the bad outcomes associated with early sexual activity through a government that was designed to do just exactly the opposite of it.

Mr. Souder. Dr. Zenilman, because one of the things we are arguing here are outcomes, and you did a study, you were the lead author, in 1995. And if I can quote from this, I would like to hear your comments on it. That 15 percent of the men who were always condom users had incident sexually transmitted diseases, compared with 15.3 percent of those who never used condoms, 23.5 percent of the women who were always users in incident sexually transmitted diseases, compared to 26.8 percent of never users. This study did not determine if subjects were infected with HPV, it should be pointed out.

In your study there was no significant statistical difference between men and women who always used condoms and those who never used condoms. So how do you explain that study? I would be interested.

Dr. Zenilman. Sure. I would be happy to. The title of the study was the validity of self-reported condom use, and the question that was asked was can we use sexually transmitted diseases as a biological marker of condom use. And there is subsequent data to support our hypothesis from other areas, that if you are actually asking somebody within a clinic environment, where the messages are to use condoms all the time, and you are seeing them, that we understand that a certain proportion of people will over-estimate their condom use. In a sense, there is an incentive to say that they use when they did not. So the question in that study was actually not on the efficacy of condom use, but, rather, do patients really tell the truth about their condom use and are there ways that we can develop methods from a behavioral standpoint or from a biological measure to measure that more accurately. I stated actually in the text of the discussion of that article that was really the specific objective of the study and what our hypothesis was.

Mr. Souder. So the fact that there were no significant difference between usage of condoms and not, you assumed that your people were lying.

Dr. Zenilman. That is correct.

Mr. Souder. How did you confirm that they were lying?

Dr. Zenilman. Well, embedded in this study there were a large number of partnerships. We never had enough data to actually publish this as a formal manuscript, but if we asked partners of men who said that they used condoms, the men said they used condoms 100 percent of the time. We had a certain number of female partners in that study and we actually looked at the same question and how they responded to the question,

and there was no correlation.

Mr. Souder. How did you know they weren't lying?

Dr. Zenilman. Somebody is.

Now, on a subsequent issue, actually, we do have some more recent biological markers which we are analyzing from that same study.

Mr. Souder. Because whenever you get into sexual activity questions, for example, some believe that the number of people who say they are sexually active in certain periods of time in American history will be exaggerated; in other times, when there is a public message that stresses more abstinence, the number of people who say they are abstaining is exaggerated. The problem with this is to make claims based on data where you don't know whether your subjects are lying seems to be a rather tenuous proposition.

Dr. Zenilman. Well, with all due respect, sir, that actual paper had been through several series of peer review by journals and had been presented at a number of national meetings and has been validated in subsequent studies. I would be happy to share that with you.

Mr. Souder. I wasn't even necessarily referring to your paper, because if your assumption is correct that there is a certain percentage lying, if you agree that a certain percentage lie depending on other variables in the society on whether they are abstaining or not abstaining, this whole question of scientifically saying effectiveness is in fact somewhat challengeable, to say the least, because you can't establish who is and who isn't, and, therefore, the scientific argument that it is effective is fairly shaky.

Dr. Zenilman. I think that was a specific objective of the NIH committee which was mentioned. And as I am sure you are well aware, there was a subsequent research meeting which actually established a number of research priorities for the NIH and other HHS agencies to investigate this specific issue. I mean, that is recognized as a research question.

Mr. Souder. Dr. Coburn, do you have any comments on this?

Dr. Coburn. I would just say we are seeing the same thing in HIV right now. There are studies out there where people say they tell their partners but don't; and then there are those that say they always use condoms but don't. So the data is skewed based on the lack of truthfulness based on the question that is asked. There is a prejudice when you ask the question, because right now, today, in today's climate, it is important for people who are HIV-infected to always use a condom, it works 86 percent of the time. Well, if they are not, but the standard in the society is to use it, you are going to get an answer that they use it, even though what we know when we have people actually inside the groups that are participating and actually participating in that behavior, what we see is a very different story. And that is why we are seeing, in the gay community, a rise in new infections, because they are not using condoms anymore, because we have done great research in terms of the successful control of the disease for a great many people.

So I think all data is hard to get, and I think this study is important in terms of telling us not about whether there is a comparison of sexually transmitted diseases with condoms or

without. It is important in terms of saying it is hard to get truthfulness in some of this, and I think it is true.

I would also say Dr. Cox has been responsible, to a great extent, for our change in how we handle cervical cancer, especially abnormal Paps. This has changed over 5 to 6 years. We are not as aggressive as we used to be because of some of the research that has come on that, and I think that needs to be said, because that knowledge of HPV in terms of low-risk, we aren't as aggressive as we were in the past, and we don't have to be because of some of the research that they have put forth.

Mr. Souder. Well, we have had you here for a long time. Let me finish this way. And we will go in reverse order, so you get the first chance. Most of you have come as far as the others, but we will have you start. And I will let you make any comments you want after having heard what each of you said in this panel and what you have heard at the hearing today.

Dr. Zenilman.

Dr. Zenilman. So it is a general open?

Mr. Souder. Yes. Open mic time.

Dr. Zenilman. Right. First of all, I want to thank you and the committee for inviting us. I think really, from what I have heard, there is less disagreement than actually may be innately obvious, because I think the basic messages are there and I think we are in agreement on. I think it is specifically how it is framed. And I think if we could take a little bit of the acrimony out of this, we may be able to be more able to craft a message which is consistent with what everybody wants.

Mr. Souder. Thank you.

Dr. Meeker.

Dr. Meeker. Thank you. I totally agree. I think that, obviously, when you talk about sexual activity and sexual behavior, it is pretty easy for me, because I am talking about kids, and everybody is innately protective of kids, so I am very glad I am not an internist and talking about sexual behavior of 25-year-old women. That is your job. But I think that it is a very emotional topic and one of the great difficulties for us, and I do agree that we are in much more agreement than we believe, is that with the talk and the discussion about the very seriousness of HPV infections and cervical cancer is completely shifting the way we need to approach and rethink condom use.

Heretofore, I believe the general public has believed, and many physicians like me have believed, that condoms are a panacea. And the reason we thought that was pretty well founded, because condoms do work better, to use non-medical language, with HIV than they do with HPV. That is just the way it is. And we felt very secure and safe in just teaching people just use condoms, use condoms, different colors, different flavors, different whatever; anything we needed to do. But this is a new day, and now it is time to attend to the needs of our young women.

Cervical cancer is a young woman's disease. I am a pediatrician here talking about STDs. Isn't that sad? And so we need to dramatically shift our paradigm in how we think and approach sexually transmitted diseases. And I don't hate condoms, but I know that I took an oath 20-some years ago to provide the best medical care that I can to my patients, and as

far as cervical cancer that I see in my young women, it is unabashedly to teach them to delay sexual activity as long as possible and to reduce the number of partners; and that is where I will go down fighting for that in years to come, because that is what the young girls in my practice need to hear, and I think the medical community is agreed on that.

We need some serious Federal money and energy in that. We have given it to the HIV/AIDS community, which is wonderful; we are making great strides. Now it is time to turn to our young women and say we will teach you very aggressively to hold off on sexual activity as long as possible. And we really need to be willing to step forward into new territory in that way.

And I thank you for the opportunity to be here.

Mr. Souder. Thank you.

Dr. Cox, you have come the farthest.

Dr. Cox. And have to go back the farthest tonight, yes, and be back in the clinic tomorrow morning.

I think in most ways we are in agreement. I think, as I said when I started out this discussion earlier, we all agree that delaying intercourse as long as possible is in everybody's benefit, and that is the primary message that should be taught in our sex education classes. I feel very strongly, though, that we need comprehensive sex education that includes all the messages, including those of how to best protect one's self when you do become sexually active; and that they need to be realistic messages. Young people need to be taught that condoms are not 100 percent effective and that they don't work as well for HPV as they do for HIV. But I think that to eliminate or at least diminish the potential of their use would be quite detrimental and might increase the risk of HIV.

I disagree on one statement that was just made, that cervical cancer is a young woman's disease. Cervical cancer is really non-existent, or almost so, below the age of 21. The serious statistics in the last few years have not shown any cervical cancers per 100,000 women in women 21 or below, but 21 to 24 there is 1.7 per 100,000 women that get cervical cancer. And of course, the rates go up and start to plateau off in the forties. I guess we can still call that young women in the forties. But I would agree, though, that the risk of getting cervical cancer is an issue that is increased by having intercourse and getting exposed to high-risk HPV in very young women and teens, and that is where the risk is; it is not that there are great risks of cervical cancer then, but certainly that exposure then puts them at greater risk than if they had gotten exposed to the virus later in life. And we need to make sure that our young women know that.

And if anybody wants to go to the briefing on HPV that I am going to do right after this, I am certainly going to stress the issues in terms of education of our children, that they can't be totally protected by condoms against HPV, and that this virus is most risky when they are at that age. We would like very much to get motivation to delay intercourse, but we also want to make sure that, as we prepare our children to be adults, that they have at least the tools, when they become adults, to protect themselves.

Mr. Souder. Can I ask you a technical question? Pardon my ignorance. Does the cervical cancer through HPV, does it

incubate a number of years? In other words, could you be exposed to it when you are young and then have it show up?

Dr. Cox. Most HPV does, if it is going to express itself, goes through some cellular expression within a couple of years of exposure, but some perhaps may lay in what we call a non-express or latent phase for a number of years and then immunity decreases. And they haven't cleared the virus, which most do, but if it goes a number of years and they haven't, it then may express itself. But I think probably most get some expression early on. And when you get a high-grade lesion in a young women, typically those high-grade pre-cancers will be present for many, many years before they attain the capability of being invasive. So the reason that cervical cytology has diminished the risk and the rate of cervical cancer so dramatically is the capability of picking up those high-grade changes before they become invasive cancer, and treating them.

Mr. Souder. If you have the pre-cancer lesions and so on, does that make it more likely that you could be exposed from further sexual activity with different partners later in your life? Is there any kind of reoccurrence vulnerability that develops?

Dr. Cox. It is interesting. Most of the studies that have looked at women as they age have shown that with increasing number of partners, individuals appear to become immune to increasing number of types, so that getting exposed to HPV again, they may become less likely to be HPV positive. Of course, increasing number of partners also increases the risks that they may have a viral type that isn't cleared and may eventually get cervical cancer.

But I am not sure I totally answered your question.

Mr. Souder. I wouldn't totally understand it if you totally answered it anyway. I was just trying to get a basic understanding. Thank you.

Dr. Bush.

Dr. Bush. I was just going to piggy-back on that response. The Medical Institute for Sexual Health has published a monogram on condoms, and in it it talks about the cumulative effect of repeated infections, and that does put you at risk for cervical cancer.

What I was going to originally say was that I have been in women's health for 35-plus years, and when I first started, principally dealing with childbirth, when we talked about the use of condoms, it was always derided as the least effective form of contraception. And that is mostly what condoms were used for. And, of course, 100 percent effective was your hormonal contraceptives, and so condoms were considered 85 percent effective for prevention of pregnancy, and we considered that worthless.

It is interesting to me now we say condoms are 85 percent effective for prevention of HIV and we call it highly effective. So that is kind of confusing. I don't know if the 35 years made the difference or what, but that is interesting.

I also wanted to add that when a woman gets infected with HPV, then the persistence of infection is the thing that gives her the increased risk. We don't know which woman is going to get rid of the infection with her immune status and which one is going to persist. So it is like when I am counseling a woman

to use the best method to prevent an infection, prevent an infection, then not knowing her immune status, I am going to give her information that will put her at the greatest health-promoting method, and that would be to abstain from sex, to delay sex, to limit her partners, because I feel like I am giving her the best recommendation, to modify her behavior, that will promote the best for her long-term. I too am the mother of children, and this is what I tell my kids, so I feel like it would be unethical for me to tell my patients anything less than the best.

The YRBS study that was put out by the CDC showed that 50 percent of young people are now reporting that they are abstaining from sex, so I feel like the best method to delay sexual activity is having an effect. And I am encouraged by the fact that in the study, when they broke it out with ethnic minorities, the group that showed the greatest progress toward abstinence, increasing their rates of abstinence, were African-American youth. So I feel like the message is being put out there, is being heard, and I would like to see us put as much effort, as much money, as much resources into promoting the method that will give you the best health, that will be primary prevention, as opposed to a second tier, which is the condom.

Mr. Souder. Thank you.

Dr. Coburn.

Dr. Coburn. Well, thank you for having this hearing. I think it is important. I still am skeptical that the FDA and the CDC will come up to the bar that they need to. They have made statements; it is my hope that they will do that.

I was just kind of wondering and thinking out loud what if every one of our children aged 12 years and older was taught about HPV and what the consequences would be. What would the behavior change be if they were actually taught in school here is a virus, here is how you get it, here is what is going to happen. I will tell you what would happen: the vast majority of them would delay the onset of sexual activity. And what we are talking about when we talk about abstinence is a realistic look at what are the consequences if you have a behavior other than that. And we are afraid to tell our children the truth, as far as the Government is concerned, and it is time that changed. Our children are worth more than that. We ought to invest in them. We ought to trust them that the majority of the time they are going to make good decisions. They are not going to make bad decisions all the time. And then we ought to support them at the time when they make a bad decision.

The other thing is that Congress ought to continue to support HPV vaccine research, but it needs to be a broad multivalent vaccine. Going after one or two types is halfway, and if we put money into that instead of a good solution to it, a good secondary treatment option rather than prevention, I think we will have failed. So I think oversight in terms of what the CDC and the FDA are doing in terms of vaccines are very important, because if we just go after HPV-16, what we are going to see is the other viruses rise in terms of prevalence, if we haven't decreased the age of onset and the number of partners.

So I thank you for holding this hearing. Prevention is the best message for our youth, and the best message with that is

knowledge associated with sexually transmitted disease and an attitude of abstinence. We use that method on every other area where they are at risk; there is no reason that good leadership couldn't use that method on this.

Mr. Souder. Well, thank you very much. We will put your full statements in the record. If you have anything else to add, we may have a few written questions for you before we close the hearing record.

With that, the subcommittee stands adjourned.

[Whereupon, at 2:43 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Additional information submitted for the hearing record follows:]

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